Peilbrief nr	Vakgroep	Ontwikkeling of risic	Bericht nr	Titel	Bron	Datum bericht	Product	Product categorie	Onderwerp	Onderwerp categorie	Inhoud bericht	Internetlink	Additionele bron(nen)
32	Klinische technologie	Risico	1	EXCEL finds repeat revascularisations following both CABG and PCI lead to increased mortality	CardioVasculer News	16-jan	coronary drug-eluting stent	02 Viet actief implantaat	PCI (DES) versus CABG	11 Overig	A secondary analysis of repeat revascularisation in the EXCEL trial has found that it was associated with increased mortality after both percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) in patients with left main coronary artery disease (LMCAD). The EXCEL investigators also noted that, consistent with previous studies, repeat revascularisation was performed less frequently following CABG than PCI, and suggest this may have contributed to the higher rate of all-cause mortality seen with PCI in EXCEL. The findings of the main EXCEL trial have been the subject of much recent debate, including the incidence of myocardia infarction, which was not measured according to the universal definition.	https://cardiovascularnews.com/excel-finds-repeat-revascularisations-following-both-cabg-and-pci-lead-to-increased-mortality/	https://www.medscape.com/viewarticle/923927
32	Implantaten	Ontwikkeling	2	Abbott becomes first company in world to have transcatheter mitral implantation device on market	CardioVasculer News	30-jan	Tendyne transcatheter mitral valve implantation system	02 Viet actief implantaat	CE-markering	12 Markttoelating	The Tendyne transcatheter mitral valve implantation (TMVI) system (Abbott) has received the CE mark, making Abbott the first company to have such a device on a market anywhere in the world. A press release reports that this "life-changing" therapy treats significant mitral regurgitation in patients requiring a heart valve replacement and provices a safe and effective solution for patients who are not candidates for open-heart surgery or transcatheter mitral valve repair.	https://cardiovascularnews.com/abbott-becomes-first-company-in-world-to-have-transcatheter-mitral-implantation-device-on-market/	http://www.crtonline.org/news-detail/tendyne-transcatheter-mitral-valve-gets-ce-mark-in https://www.medgadget.com/2020/01/abbotts-tendyne-first-transcatheter-mitral-valve-to-win-eu-clearance.html https://www.fierceb
32	Klinische technologie	Risico	3	EXCEL may damage relations between interventional cardiologists and cardiac surgeons	CardioVasculer News	6-feb	coronary drug-eluting stent	02 Viet actief implantaat	PCI (DES) versus CABG	11 Overig	The debate over the results of EXCEL shows no sign of abating, and there seems to be a division between cardiac surgeons and interventional cardiologists about which side of the argument they fall on, with surgeons generally supporting EACTS, and interventional cardiologists generally supporting the EXCEL leadership. Although some interventional cardiologists do not believe the disagreements will change their practice, they raise concerns that their working relationships with surgeons may suffer.	https://cardiovascularnews.com/excel-may-damage-relations-between-interventional-cardiologists-and-cardiac-surgeons/	
32	Klinische technologie	Risico	4	JIM 2020: Weigh up early and late events in EXCEL to determine treatment for left main disease	CardioVasculer News	14-feb	coronary drug-eluting stent	02 Viet actief implantaat	PCI (DES) versus CABG	11 Overig	Gregg W Stone (Icahn School of Medicine, Mount Sinai, New York, USA) addressed the EXCEL controversy today at the Joint Interventional Meeting (JIM 2020, 13–15 February, Milan, Italy), stipulating that although percutaneous coronary intervention (PCI) has early advantages and coronary artery bypass graft (CABG) confers late advantages, in the long term there are no significant major differences in long-term survival, major adverse cardiovascular events (MACE: death, myocardial infarction [MI], or stroke), or quality of life between the two procedures.	https://cardiovascularnews.com/jim-2020-weigh-up-early-and-late-events-in-excel-to-determine-treatment-for-left-main-disease/	
32	Klinische technologie	Risico	5	BBC Newsnight makes fresh claims about allegedly withheld mortality data in EXCEL	CardioVasculer News	19-feb	coronary drug-eluting stent	02 Viet actief implantaat	PCI (DES) versus CABG	11 Overig	The news programme BBC Newsnight has made further claims that the EXCEL investigators "held back" data from the published results of the left main trial. In a programme that aired on 18 February, reporter Deborah Cohen claims that Gregg Stone (The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, USA) and colleagues could have published mortality data in 2016 that showed that "more people had died" with stents.	https://cardiovascularnews.com/bbc-newsnight-make-fresh-claims-about-allegedly-withheld-mortality-data-in-excel/	https://www.ictmd.com/news/bbc-makes-new-excel-allegations-says-investigators-ignored-safety-concerns
32	Systeem	Ontwikkeling	6	DNV GL achieved designation by the Norwegian Health Authorities and the European Commission as a Notified Body for Medical Devices Regulation (EU) 2017/745 (MDR)	DNV.GL	6-feb	medische hulpmiddelen	16 Wet en regelgeving	Designation of NoBo	05 Standaardisatie, wet-/regelgeving/NoBo	DNV GL is delighted to announce their Notified Body 2460 in Oslo successfully achieved designation by the Norwegian Health Authorities and the European Commission as a Notified Body for Medical Devices Regulation (EU) 2017/745 (MDR). The designation was successfully granted for all technology types applied for, including the highest risk Class III devices, ensuring continuity of European market access for our customers' life-saving medical technology.	https://www.dnvgl.com/services/medical-devices-regulation-eu-2017-745-mdr-138310#	
32	Klinische technologie	Risico	7	New Paclitaxel Meta-Analysis Questions Safety in CLI Population; Concerns Voiced as to Methods	Endovascular Today	15-jan	paclitaxel gecoate ballonnen	20 Overig	meta-analyse paclitaxel gecoate ballonnen	11 Overig	In the wake of a year spent scrutinizing the finding of a mortality signal related to paclitaxel-coated balloons and stents in the superficial femoral artery (SFA), a new publication again calls the safety of paclitaxel into question, only this time in the critical limb ischemia (CLI) population. The results of a systematic review and meta-analysis of paclitaxel-coated balloons published today in the Journal of Vascular and Interventional Radiology (JVIR) by Katsanos et al echo those of the authorship group's December 2018 article in the Journal of the American Heart Association (JAHA), showing reduced need for reintervention but also lower amputation-free survival through 12 months. It also appears likely that considerable debate surrounding the methods and conclusions will follow the publication, as it did the preceding study.	https://evtoday.com/news/new-paclitaxel-meta-analysis-questions-safety-in-cli-population-concerns-voiced-as-to-methods	https://interventionalnews.com/amputation-paclitaxel-katsanos/ https://www.medscape.com/viewarticle/924904
32	ICT, eHealth & Domotica	Ontwikkeling	8	FDA Market-Approves First AI-Based Echocardiography Software	Medscape	7-feb	Caption Guidance	18 Artificial intelligence	FDA approval	12 Markttoelating	The US Food and Drug Administration (FDA) has granted marketing approval to what it calls the first echocardiography software that uses artificial intelligence (AI) "to guide users through cardiac ultrasound image acquisition," the agency announced today.	https://www.medscape.com/viewarticle/924956?nlid=133905_3865&src=WNL_mdplsfeat_200211_mscpedit_card&uac=61059SR&spon=2&impID=2275532&faf=1	https://www.fiercebiotech.com/medtech/fda-approves-ai-guides-untrained-clinicians-capturing-

32	Implantaten	Ontwikkeling	9	New Device for Intracranial Aneurysm Approved in Europe	Medscape	18-feb	Contour Neurovascular System	02 Niet actief implantaat	CE-markering	12 Markttoelating	Cerus Endovascular has announced that it has received European CE Mark approval for its lead product, the Contour Neurovascular System, for the treatment of intracranial aneurysms. Contour Neurovascular System represents a new, and potentially disruptive, standalone solution for the treatment of bifurcated saccular intracranial aneurysms compared to currently available technologies.	https://www.medscape.com/viewarticle/925374	
32	Klinische technologie	Risico	10	Paclitaxel Controversy Is Causing CE Mark Delays for New Paclitaxel Devices	MDDI	6-feb	paclitaxel gecoate ballonnen	20 Overig	CE-markering	12 Markttoelating	Tension over stents and balloons that are either coated with or are designed to release paclitaxel has eased up in the United States, but across the pond may be a different story. The meta-analysis published in late 2018 that showed an increased risk of death for patients treated with paclitaxel devices seems to have given European regulators pause with regards to these devices. Eden Prairie, MN-based Surmodics submitted all the required modules for its SurVeil drug-coated balloon (DCB) to the European notified body before the end of the company's fiscal year 2019, but CEO Gary Maharaj said the organization has temporarily halted CE mark reviews for new paclitaxel devices pending more follow-up data from studies on current paclitaxel devices.	https://www.mddionline.com/paclitaxel-controversy-causing-ce-mark-delays-new-paclitaxel-devices	
32	Systeem	Ontwikkeling	11	Icon snaps up medical device CRO MedPass International	FierceBiotech	25-feb	CRO	20 Overig	overname CRO	11 Overig	Icon is boosting its medical device and diagnostic research offering with a buyout deal for Parisian medtech CRO MedPass International.	https://www.fiercebiotech.com/cro/icon-snaps-up-medical-device-cro-medpass-international	
32	Klinische technologie	Risico	12	No Mortality Difference Observed in JEVT Meta-Analysis of CLTI Patients Treated With Paclitaxel	Endovascular Today	21-feb	paclitaxel gecoate ballonnen	20 Overig	meta-analyse paclitaxel gecoate ballonnen	11 Overig	Investigators seeking to explore the risks of paclitaxel-coated devices (PCDs) in patients with chronic limb-threatening ischemia (CLTI) have published a new meta-analysis finding no difference in short- to midterm mortality versus outcomes in patients treated with uncoated devices. The study comes on the heels of a similar meta-analysis published in the Journal of Interventional Radiology (JVIR) by Katsanos et al in January 2020, although the studies differ in their inclusions, methods, and results.	https://evtoday.com/news/no-mortality-difference-observed-in-jevt-meta-analysis-of-clti-patients-treated-with-paclitaxel	
32	Medische hulpmiddelen	Ontwikkeling	13	Fist Assist Device Approved and Launched in Europe	Endovascular Today	21-feb	Fist Assist	06 Wearables, incl sensoren op huid	CE-markering	12 Markttoelating	Fist Assist Devices, LLC, announced CE Mark approval for its wearable Fist Assist intermittent compression device to increase vein diameter before fistula placement and to assist in fistula vein dilation for hemodialysis for end-stage renal disease patients. Fist Assist provides a patient-focused evidence-based approach to surgical vein enhancement for all types of arteriovenous fistulas and can be used to enhance veins before fistula creation as well as after surgery to improve maturation. Fist Assist is a creative solution which for the first time allows patients to be involved and directly influence their clinical outcomes with a comfortable and easy to use device.	https://evtoday.com/news/fist-assist-device-approved-and-launched-in-europe	
32	Klinische technologie	Risico	14	Meta-analysis Questions PCI vs CABG in Women With Multivessel Disease	TCTMD	27-feb	PCI vs CABG	20 Overig	meta-analyse PCI vs CABG in vrouwen	11 Overig	There are new data hinting that women with multivessel disease may do better with CABG than with PCI, this time from a meta-analysis of 15 trials, although only a minority of these included gender-specific data.	https://www.tctmd.com/news/meta-analysis-questions-pci-vs-cabg-women-multivessel-disease	
32	Klinische technologie	Ontwikkeling	15	Tumoren beter zichtbaar tijdens operatie.	Radboudumc	10-feb	fluorescentie, radioactiviteit én de tracer die zich specifiek bindt aan kwaadaardige cellen	11 Beeldvormende/bestraling s technieken	nieuwe methode	02 Nieuwe therapie/techniek	De resultaten van dit eerste onderzoek werden gepresenteerd in het vaktijdschrift Theranostics en zijn veelbelovend. De methode bleek te werken. Hiermee was Rijpkema's onderzoeksgroep wereldwijd de eerste die deze methode, waarin fluorescentie, radioactiviteit én de tracer die zich specifiek bindt aan kwaadaardige cellen gecombineerd werd, succesvol toegepast bij patiënten. Er werd al op meer plaatsen gewerkt met radioactieve tracers en ook wel met lichtgevende stoffen, maar de combinatie met de specifieke tracer was nog niet eerder vertoond.	https://www.radboudumc.nl/nieuws/2020/tumoren-beter-zichtbaar-tijdens-operatie	
32	ICT, eHealth & Domotica	Ontwikkeling	16	€75 miljoen voor digitale uitwisseling medische gegevens	ICT&health	11-feb	wetsvoorstel	05 EPD/ patientgegevens	extra subsidie voor uitwisseling patientgegevens	06 Economisch nieuws	Minister Bruins zal dit jaar nog een wetsvoorstel indienen om ziekenhuizen en klinieken te verplichten onderling digitaal gegevens uit te wisselen. Om snel aan die wet te kunnen voldoen wordt 75 miljoen euro subsidie beschikbaar gesteld. Uiteindelijk wil Bruins dat alle ziekenhuispatiënten online, in een persoonlijke gezondheidsomgeving, hun eigen medische gegevens kunnen inzien, delen of koppelen aan apps	https://www.icthealth.nl/nieuws/e75-miljoen-voor-digitale-uitwisseling-medische-gegevens/	https://www.nationalezorggids.nl/ziekenhuizen/nieuws/52463-75-miljoen-voor-digitale-toegang-patient-in-eigen-medisch-dossier.html
32	ICT, eHealth & Domotica	Risico	17	Weinig bewijs voor betrouwbaarheid huidkankerapps	medisch contact	13-feb	huidkankerapp	04 App	huidkanker app onbetrouwbaar	03 Waarschuwing/incident	De kwaliteit van het bewijs voor betrouwbaarheid van smartphoneapps die huidafwijkingen beoordelen, is slecht. Dit blijkt uit een review van Karoline Freeman e.a. in The BMJ. De auteurs concluderen dan ook dat de huidige manier waarop deze apps een CE-markering hebben gekregen, niet voldoet. En dat men (nog) niet kan vertrouwen op deze apps om alle huidkankergevallen op te sporen.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/weinig-bewijs-voor-betrouwbaarheid-huidkankerapps-.htm	
32	ICT, eHealth & Domotica	Ontwikkeling	18	Brailletoetsenbord in race voor Global Student Entreprencur Award	technisch weekblad	14-feb	brailletoetsebord	07 Overig ICT	brailletoetsenbord voor smartphones	01 Nieuw product	TU/e-startup Hable Accessibility ontwikkelt een brailletoetsenbord voor smartphones waarmee blinden via braille teksten kunnen tikken op hun smartphone en kunnen swipen door webpagina's. Hable is een add-on bluetooth braille toetsenbord die blinden in staat stelt tekst in te voeren en de smartphone eenvoudiger te bedienen	https://www.technischweekblad.nl/nieuws/brailletoetsenbord-in-race-voor-global-student-entrepreneur-award	https://www.cursor.tue.nl/nieuws/2020/februari/week-2/brailletoetsenbord-in-race-voor-global-student-entrepreneur-award/, https://www.ictheallth.nl/nieuws/award-voor-eerste-draadloze-smartphone-braille-toetsenbord/

32	ICT, eHealth & Domotica	Ontwikkeling	19	'Slimme software' herkent vroege vormen slokdarmkanker	fmt gezondheidszorg	21-feb	computeralgoritme	07 Overig ICT	computeralgoritme	10 Nieuwe ontwikkeling	Slimme software kan tijdens een endoscopie de vroege tekenen herkennen van slokdarmkanker bij patiënten met een zogenoemde 'Barrett-slokdarm'. Dit blijkt uit onderzoek van Amsterdam UMC, de Technische Universiteit Eindhoven (TU/e) en het Catharina Ziekenhuis uit Eindhoven. Zij publiceerden onlangs de resultaten in de toonaangevende medische tijdschriften Gastroenterology en Gastrointestinal Endoscopy. Het nieuwe computeralgoritme geeft op een beeldscherm een rode markering bij een verdachte plek. De arts kan dan handelen door het verdachte gebied nader te inspecteren en bijvoorbeeld een biopt te nemen.	https://fmtgezondheidszorg.nl/slimme-software-herkent-vroege-vormen-slokdarmkanker/	
32	Systeem	Ontwikkeling	20	Herziening kwaliteitsmanagementnorm voor medische laboratoria ter commentaar	fmt gezondheidszorg	21-feb	NEN-EN-ISO 15189	16 Wet en regelgeving	herziening norm	05 Standaardisatie, wet-/regelgeving/NoBo	NEN-EN-ISO 15189 'Medische laboratoria – Bijzondere eisen voor kwaliteit en competentie' zit in het internationale herzieningsproces. De norm is binnen medische laboratoria een bekend begrip. De leden van de normcommissie 'IVD' hebben tot begin april om op de herziening, namens Nederland, te reageren.	https://fmtgezondheidszorg.nl/herziening-kwaliteitsmanagementnorm-voor-medische-laboratoria-ter-commentaar/	
32	In-vitro diagnostica	Ontwikkeling	21	Griep in twintig minuten op te sporen met sneltest	fmt gezondheidszorg	5-feb	sneltest	08 POC test/zelftest	sneltest voor influenza griep	01 Nieuw product	Het Maastricht UMC+ heeft op de Spoedeisende Hulp (SEH) sinds kort de beschikking over een sneltest voor griep. Door het afnemen van een beetje keelslijm (via een wattenstaafje) kan in twintig minuten worden bepaald of iemand het griepvirus onder de leden heeft. Voordat de sneltest beschikbaar was, werden patiënten die verdacht werden van een griep-besmetting geïsoleerd opgenomen.	https://fmtgezondheidszorg.nl/griep-in-twintig-minuten-op-te-sporen-met-sneltest/	
32	Medische hulpmiddelen	Ontwikkeling	22	Qwiek introduceert slim muziekkussen voor mensen met dementie	fmt gezondheidszorg	23-jan	muziekkussen	20 Overig	muziekkussen om in slaap te vallen	01 Nieuw product	Zorginnovatiebedrijf Qwiek brengt dit jaar een nieuw product op de markt voor mensen met slaapproblemen: de Qwiek snooze. De muziekkusseninterventie is inmiddels door Vilans (de landelijke kennisorganisatie voor langdurende zorg) erkend als "theoretisch goed onderbouwde interventie" in de langdurige zorg.	https://fmtgezondheidszorg.nl/qwiek-introduceert-slim-muziekkussen-voor-mensen-met-dementie/	
32	Klinische technologie	Ontwikkeling	23	Nieuw medisch hulpmiddel voor zeer complexe dotterbehandelingen	fmt gezondheidszorg	8-jan	Telescope Guide Extension Catheter	12 Operatie instrument	nieuwe catheter	01 Nieuw product	Het Catharina Hart- en Vaatcentrum is het eerste centrum in Nederland dat een nieuw product in gebruik heeft genomen voor zeer complexe dotterbehandelingen. Het gaat om de Telescope Guide Extension Catheter van Medtronic. Deze katheter stelt gespecialiseerde cardiologen in staat om op moeilijk te bereiken plekken binnen het vaatstelsel te komen.	https://fmtgezondheidszorg.nl/nieuw-medisch-hulpmiddel-voor-zeer-complexe-dotterbehandelingen/	
32	Implantaten	Ontwikkeling	24	Doorslikbare maagballon in de strijd tegen obesitas groot succes	medicalfacts	3-jan	elipse maagballon	02 Niet actief implantaat	maagballon populair	11 Overig	Door een toenemende vraag wordt het aantal locaties waar de Elipse-maagballon kan worden geplaatst in 2020 uitgebreid. De maagballon is bedoeld voor patiënten met overgewicht die nog niet in aanmerking komen voor een maagverkleining. De behandelmethode is revolutionair, omdat de ballon in twintig minuten wordt geplaatst, zonder medische ingreep. De innovatieve behandelmethode leidt gemiddeld tot een gewichtsverlies van 15 kilo.	https://www.medicalfacts.nl/2020/01/03/doorslikbare-maagballon-in-de-strijd-tegen-obesitas-groot-succes/	
32	ICT, eHealth & Domotica	Ontwikkeling	25	Medisch dossier opslaan in onderhuidse 'tattoo'	ICT&health	20-jan	medisch dossier	06 Wearables, incl sensoren op huid	dossier in de huid	10 Nieuwe ontwikkeling	Wetenschappers van MIT hebben een manier ontwikkeld om medische informatie over vaccinaties onder de huid, als een onzichtbare tattoo, op te slaan. Dit gebeurt met behulp van een speciale, voor het oog onzichtbare, kleurstof. Deze wordt met een micronaaldpleister onder de huid aangebracht en kan tegelijkertijd ook dienen om vaccinaties toe te dienen. De informatie van het 'medisch dossier' die in 'tattoo' opgeslagen is kan met een aangepaste smartphone uitgelezen worden. Tests met op menselijke huid toonden aan dat de quantum-dot-patronen na maximaal vijf jaar nog konden worden uitgelezen. Tijdens de test werd vijf jaar blootstelling aan zonlicht gesimuleerd.	https://www.ichealth.nl/nieuws/medisch-dossier-opslaan-in-onderhuidse-tattoo/	
32	ICT, eHealth & Domotica	Risico	26	Weinig ziekenhuizen met Citrix-problemen	medisch contact	22-jan	citrix-problemen	07 Overig ICT		03 Waarschuwing/incident	De problemen met veiligheid van Citrix-servers heeft voor de meeste ziekenhuizen en zorginstellingen in Nederland beperkte gevolgen gehad. Dat concludeert kennisplatform ICT&Health na een rondje langs de websites van ongeveer negentig ziekenhuizen en zorginstellingen.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/weinig-ziekenhuizen-met-citrix-problemen-.htm	
32	Systeem	Ontwikkeling	27	Meldplicht implantaten uitgebreid én ingeperkt	medisch contact	24-feb	Landelijk Implantaten Register	16 Wet en regelgeving	aanpassing LIR	05 Standaardisatie, wet-/regelgeving/NoBo	De meldplicht voor medische implantaten wordt uitgebreid. Het is de bedoeling dat vanaf eind mei alle zogenaamde hoogrisico-implantaten worden vermeld in patiëntdossiers en het Landelijk Implantaten Register. Op maat gemaakte implantaten worden juist uitgezonderd van deze meldplicht.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/meldplicht-implantaten-uitgebreid-en-ingeperkt.htm	
32	ICT, eHealth & Domotica	Ontwikkeling	28	Wet gegevensuitwisseling stelt eisen aan ICT, beveiliging	ICT&health	26-feb	wet gegevensuitwisseling	05 EPD/ patientgegevens	eisen aan beveiliging	05 Standaardisatie, wet-/regelgeving/NoBo	De nieuwe Wet elektronische gegevensuitwisseling in de zorg zal bepalingen bevatten die het mogelijk maken om eisen te stellen aan, onder meer informatieveiligheid en privacy. Ook worden bepalingen opgenomen die certificering van ICT-producten mogelijk maken. Dat stelt minister Bruins van Medische Zorg & Sport in reactie op Kamervragen naar aanleiding van de Citrix-problematiek afgelopen januari. Bruins benadrukt echter dat zorgaanbieders primair zelf verantwoordelijk blijven voor hun ICT en informatieveiligheid.	https://www.ichealth.nl/nieuws/wet-gegevensuitwisseling-stelt-eisen-aan-ict-beveiliging/	
32	ICT, eHealth & Domotica	Risico	29	Rode Kruis sluit AED-database	skipr	27-feb	AED's	04 App	AED's locatie niet meer in app	03 Waarschuwing/incident	Het Rode Kruis in Nederland heeft donderdag zijn openbare database gesloten waarop plekken van automatische externe defibrillators (AED's) of/wel hartstarters vermeld stonden. De database was te vinden in de Rode Kruis EHBO-app.	https://www.skipr.nl/nieuws/rode-kruis-sluit-aed-database/	
32	Klinische technologie	Ontwikkeling	30	Mini cyclotron voor betere diagnose bij hartpatiënten	ict&health	10-feb	cyclotron	11 Beeldvormende/bestralings technieken	eerste minicyclotron in Europa	02 Nieuwe therapie/techniek	Het Martini Ziekenhuis in Groningen investeert in een innovatieve ontwikkeling voor de diagnostiek bij hartpatiënten. De zogenoemde mini cyclotron wordt de eerste in Europa waarin op kleine schaal radioactieve stoffen voor hartscans gemaakt worden. Het Martini Ziekenhuis gebruikt een mini-cyclotron waarin op kleine schaal radioactieve stoffen voor hartscans gemaakt worden. De stof wordt door het ziekenhuis gebruikt in een PET CT-scanner. Dit onderzoek kan nauwkeurig het zuurstoftekort in het hart in beeld brengen.	https://www.ichealth.nl/nieuws/mini-cyclotron-voor-betere-diagnose-bij-hartpatienten/	

32	ICT, eHealth & Domotica	Risico	31	Mogelijk datalek bij Gelderse ggz-kliniek na phishingmail	nationalezorggids	7-feb	datalek	05 EPD/ patiëntgegevens	datalek	03 Waarschuwing/incident	Hackers hebben mogelijk toegang gehad tot medische dossiers van honderden cliënten van een ggz-kliniek in Gelderland. Daarin staan voornamen, achternamen, geboortedata en diagnoses van mensen. Het lek ontstond nadat medewerkers in een phishingmail waren getrapt. Er zijn geen aanwijzingen dat de gegevens zijn misbruikt, laat de instelling Pro Persone weten na een bericht van RTL Nieuws	https://www.nationalezorggids.nl/ggz/nieuws/52425-mogelijk-datalek-bij-gelderse-ggz-kliniek-na-phishingmail.html	
32	In-vitro diagnostica	Ontwikkeling	32	'Urinetest toont uitzaaiing darmkanker in de lever'	skipr	17-jan	urinetest	09 Diagnostische laboratorium testen	urinetest	11 Overig	Een eenvoudige urinetest kan mogelijke uitzaaiingen van darmkanker in de lever opsporen. De nieuwe test biedt ongeveer 90 procent zekerheid, evenveel als een CT-scan. Dat concludeert Nick van Huizen van de Erasmus Universiteit in een promotieonderzoek. Huisartsen beschikken nog niet over de test. De test moet eerst nog op een grotere groep patiënten worden uitgeprobeerd. Van Huizen ontdekte na jaren van onderzoek dat mensen met een uitzaaiing van darmkanker een verhoogde hoeveelheid van bepaalde stukjes eiwit in hun urine hebben.	https://www.skipr.nl/nieuws/urinetest-toont-uitzaaiing-darmkanker-in-de-lever/	
32	Klinische technologie	Ontwikkeling	33	TULA System for Awake Ear Tube Placement FDA Approved	Medgadget	3-jan	Tula tube delivery system	12 Operatie instrument	plaatsen buisjes oren met locale verdoving	12 Markttoelating	Tusker Medical, based in Silicon Valley, has won FDA approval for its Tula System to deliver local anesthesia directly toward the ear drum and place an ear tube without any pain. Indicated for patients six months of age and older, the Tula Iontophoresis System delivers an ionized anesthetic agent, called TYMBION, and which is a combination of lidocaine and epinephrine, into the ear. The electrically charged medicine is forced to move toward the ear thanks to an electric current generated within an ear plug specifically fitted to the patient. The plugs make sure the numbing solution stays within the ear and doesn't drip out. It takes about ten minutes to deliver the local anesthetic, during which time the child is free to do whatever he/she wants.	https://www.medgadget.com/2020/01/tula-system-for-awake-ear-tube-placement-fda-approved.html	
32	ICT, eHealth & Domotica	Ontwikkeling	34	Tumor Tissue Imaging and AI Bypass Path Lab for Brain Surgeries	Medgadget	9-jan	AI voor histopathologie	18 Artificial intelligence	AI voor intraoperatieve histopathologie	10 Nieuwe ontwikkeling	In a major development in how tumors are excised, researchers at the University of Michigan have shown that it's possible to accurately analyze brain tumor tissue within the operating room and assess its nature using artificial intelligence. The new technology comes in the form of the NIO Imaging System from Invenio, a company out of Santa Clara, California. It uses stimulated Raman histology, developed at the University of Michigan, to quickly image tissues at the microscopic scale without any staining, completely bypassing the pathology lab. The technology is so fast that surgeons can take follow up actions that may prevent the tumor from regrowing without having to schedule another costly procedure.	https://www.medgadget.com/2020/01/tumor-tissue-imaging-and-ai-bypass-path-lab-for-brain-surgeries.html	
32	Klinische technologie	Ontwikkeling	35	Machine Keeps Livers Alive for a Week, Revives Injured Ones	Medgadget	14-jan	Transplantatie-lever preservator	20 Overig	verlengen levensduur transplantatie lever	01 Nieuw product	A Swiss collaboration of clinical researchers from University Hospital Zurich, ETH Zurich, Wyss Zurich, and the University of Zurich has created a machine that can keep human livers alive for up to a week. For comparison, current methods of perfusion can keep livers going for about 24 hours. Moreover, the same device can be used to rehabilitate injured livers so that they're healthy enough to be used for transplants. The multi-parameter device is described in journal Nature Biotechnology, where the researchers detail how the device, a goal of the Liver4Life project of Wyss Zurich, can manage a liver outside a human body by regulating its oxygenation, glucose levels, hematocrit control, and management of waste byproducts.	https://www.medgadget.com/2020/01/machine-keeps-livers-alive-for-a-week-revives-injured-ones.html	
32	Klinische technologie	Ontwikkeling	36	GammaTiles Help Prevent Recurrence of Malignant Brain Tumors After Surgery	Medgadget	28-jan	GammaTile, Interne bestraler	11 Beeldvormende/bestraling s technieken	FDA approval	12 Markttoelating	GT Medical Technologies, a company based in Tempe, Arizona, won FDA clearance for its GammaTiles to be used to prevent malignant brain tumors in newly diagnosed patients. The devices, about the size of a postage stamp, contain Cesium-131, a radioactive isotope with a half life of about ten days. The collagen material within which the radioactive seeds are placed is resorbable by the body and doesn't require a separate extraction procedure. This surgically targeted radiation therapy procedure was recently made available in a few hospitals for patients with recurrent brain tumors, but the new indication makes the devices, a rare new treatment, available for new cases.	https://www.medgadget.com/2020/01/gammatiles-help-prevent-recurrence-of-malignant-brain-tumors.html	
32	ICT, eHealth & Domotica	Ontwikkeling	37	Eko's AI-Powered Stethoscopes Detect AFib, Heart Murmurs	Medgadget	28-jan	Eko AI stethoscoop	18 Artificial intelligence	FDA approval	12 Markttoelating	Eko, a maker of high-end digital stethoscopes, has just received the first FDA clearance for its devices to use AI algorithms to automatically detect atrial fibrillation (AFib) and heart murmurs. Using this capability, primary care physicians, who are not nearly as extensively trained at spotting heart issues, will be able to identify potential cases of AFib, as well as vulvular and structural heart diseases, with an accuracy similar to seasoned cardiologists.	https://www.medgadget.com/2020/01/ekos-ai-powered-stethoscopes-detect-afib-heart-murmurs.html	
32	Klinische technologie	Ontwikkeling	38	Imricor's MRI-Compatible Ablation Catheters Cleared in Europe for Cardiac Arrhythmia Treatment	Medgadget	29-jan	Imicor ablatie cathethers	20 Overig	CE-markering	12 Markttoelating	Imricor Medical Systems, based outside of Minneapolis, Minnesota, has won the European CE Mark for its Vision-MR Ablation Catheter and Vision-MR Dispersive Electrode. These devices allow for cardiac ablation procedures to be performed within MRI-equipped operating rooms, thereby utilizing the accuracy of intraoperative MRI to target sources of arrhythmias.	https://www.medgadget.com/2020/01/imricors-mri-compatible-ablation-catheters-cleared-in-europe-for-cardiac-arrhythmia-treatment.html	

32	ICT, eHealth & Domotica	Ontwikkeling	39	Onera Bioimpedance Patch to Detect Sleep Apnea	Medgadget	10-feb	Sensor voor apneu diagnose buiten slaapkliniek	06 Wearables, incl sensoren op huid	klinische studie	01 Nieuw product	Onera Health, a company headquartered in Silicon Valley but with R&D offices in the Netherlands, has developed a bioimpedance patch, to be worn on the chest, that can detect sleep apnea. It has just been successfully trialed in 25 patients and the results show that it is about as accurate as automatic scoring using a traditional polysomnography respiration channel (sensitivity of 58.4%, specificity of 76.2%, and an accuracy of 72.8%). Because the device is fairly unobtrusive, and is worn on the chest, it has the potential to allow for sleep apnea diagnosis outside of sleep clinics. This may improve the quality of diagnoses, as patients will be able to perform testing under normal conditions in their own bed.	https://www.medgadget.com/2020/02/onera-bioimpedance-patch-to-detect-sleep-apnea.html	
32	ICT, eHealth & Domotica	Ontwikkeling	40	neuroQWERTY for Diagnosing, Tracking Parkinson's Wins FDA Breakthrough Device Designation	Medgadget	13-feb	Software om parkinson te detecteren via smartphone/computer gebruik	07 Overig ICT	Fda-breakthrough device designation	01 Nieuw product	Now, the FDA has granted Breakthrough Device designation to nQ Medical, a firm based in Cambridge, MA, for its neuroQWERTY software that monitors psychomotor performance and fine motor function while a person uses their computer or smartphone. The software runs in the background and the person being monitored doesn't have to do anything other than continue using the device running the neuroQWERTY software as they always have.	https://www.medgadget.com/2020/02/neuroqwerty-for-diagnosing-tracking-parkinsons-wins-fda-breakthrough-device-designation.html	
32	Klinische technologie	Ontwikkeling	41	World's First Portable MRI Cleared by FDA	Medgadget	17-feb	portable mri	11 Beeldvormende/bestraling s technieken	FDA-toelating	12 Markttoelating	Hyperfine's Lucy point-of-care MRI is intended for scanning the head, neck, as well as the extremities, in just about any clinical setting. This can be of particular use in emergency rooms, intensive care units, and in facilities that currently don't have access to a conventional clinical MRI.	https://www.medgadget.com/2020/02/worlds-first-portable-mri-cleared-by-fda.html	https://www.fiercebiotech.com/medtech/fda-clears-world-s-first-portable-bedside-mri
32	Klinische technologie	Ontwikkeling	42	Novalung FDA Cleared to Provide Long-Term Lung Failure Treatment	Medgadget	24-feb	extracorpeale beademer	20 Overig	FDA-toelating	12 Markttoelating	To help address some of the challenges of utilizing mechanical ventilation, the FDA has just cleared the Novelung System, a product of Fresenius Medical Care, that lets clinicians choose to use extracorporeal gas exchange over mechanical ventilation when managing patients for extended periods of time. The Novelung System is an all-in-one device that performs everything from CO2 exchange to oxygenation of the blood, and it has been cleared to do so for over six hours, an industry first.	https://www.medgadget.com/2020/02/novalung-fda-cleared-to-provide-long-term-lung-failure-treatment.html	
32	In-vitro diagnostica	Ontwikkeling	43	Co-Diagnostics nets European approval for its coronavirus PCR test	FierceBiotech	25-feb	Logix Smart Coronavirus COVID-19 Test	09 Diagnostische laboratorium testen	CE-markering Coronatest	12 Markttoelating	About four days after announcing the completion of its technical submissions, Co-Diagnostics said it has received European approval for its in vitro diagnostic test for the novel coronavirus, known as SARS-CoV-2. The Salt Lake City-based developer's Logix Smart Coronavirus COVID-19 Test is now available to be exported from Utah to countries requiring the CE Mark, according to the company.	https://www.fiercebiotech.com/medtech/co-diagnostics-nets-european-approval-for-its-coronavirus-pcr-test	https://www.mddionline.com/co-diagnostics-gmbs-ce-mark-coronavirus-ivd
32	Klinische technologie	Ontwikkeling	44	Cybernet unveils antimicrobial touchscreens for hospital computers	FierceBiotech	14-feb	anti-microbiele touchscreens	20 Overig	Anti-microbiele touchscreens	01 Nieuw product	Cybernet Manufacturing, maker of medical-grade computers, tablets and monitors, has unveiled a new, large touchscreen designed to resist the growth of infection-causing organisms and limit their spread throughout a hospital. Along with mold-resistant properties baked into the resin of the devices' housing, the Irvine, California-based company describes its new offerings as the world's first fully antimicrobial computers. Cybernet previously launched a 10.1-inch rugged medical tablet featuring an antimicrobial screen and exterior in early 2016. The growth-resistant properties are chemically bonded to the surface of the glass, which the company says will not degrade over time or wipe off when using cleaners or disinfectants.	https://www.fiercebiotech.com/medtech/cybernet-unveils-antimicrobial-touchscreens-for-hospital-computers	
32	Klinische technologie	Ontwikkeling	45	Illuminating cancer surgery with a dye that makes tumors glow	FierceBiotech	10-feb	luorescent dye	20 Overig	lichtgevend verf die kankercellen zichtbaar maakt.	02 Nieuwe therapie/techniek	By using a fluorescent dye that binds to cancer cells and makes them glow during surgery, researchers believe they can help make sure every piece of a person's tumor has been removed. First discovered at Purdue University and being developed by On Target Laboratories, the molecular markers attach themselves to the surface of lung and ovarian cancer cells and illuminate when viewed through an endoscope equipped with a near-infrared camera. Now, researchers have launched phase 3 trials of the intravenous dye, dubbed OTL38, in lung and ovarian cancers with a boost from previous FDA fast-track and orphan designations.	https://www.fiercebiotech.com/medtech/illuminating-cancer-surgery-a-dye-makes-tumors-glow	
32	Klinische technologie	Ontwikkeling	46	FDA approves hydrogel injection for stress urinary incontinence	FierceBiotech	4-feb	Bulkamid hydrogel	02 Niet actief implantaat	hydrogel injectie tegen incontinentie	01 Nieuw product	The FDA has approved the injection of soft hydrogel spacers designed to help firm up the walls of the urethra in women with stress urinary incontinence. By supporting the urethra's volume and increasing its natural closing pressure, the injections aim to prevent urine leakage during daily activities. Contura estimates that stress urinary incontinence affects a large percentage of women, though only a small number go on to receive treatment beyond physiotherapy—potentially in part due to the infamous risks of harmful side effects related to past surgical methods such as transvaginal mesh.	https://www.fiercebiotech.com/medtech/fda-approves-hydrogel-injection-for-stress-urinary-incontinence	

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32	Klinische technologie	Ontwikkeling	47	FDA clears Olympus' duodenoscope with additional cleaning tools	FierceBiotech	3-feb	Olympus TJF-Q190V duodenoscope	13 Scopen & camera's	Olympus TJF-Q190V duodenoscop met verbetering m.b.t. reiniging	12 Markttoelating	Following the FDA's successive clearances of new, reprocessing-conscious duodenoscope designs from Pentax Medical and Boston Scientific late last year, competitor Olympus Medical has now received a green light of its own. The agency cleared the company's TJF-Q190V duodenoscope featuring a clear, disposable endcap. Removing the single-use cap allows for easier access and cleaning of the device's complex elevator components, where bacteria and biomatter have been known to survive sterilization processes and pass infections on to the next patient. The clearance also covers a new, proprietary flushing adapter used for further cleaning of the scope's elevator mechanism—as well as water-resistant scope connectors and sealed elevator wire channels that minimize the risk of bodily fluids reaching the innards of the device.	https://www.fiercebiotech.com/medtech/fda-clears-olympus-duodenoscope-additional-cleaning-tools	
32	Klinische technologie	Ontwikkeling	48	Profusa's wireless, injectable oxygen biosensor nabs CE mark	FierceBiotech	29-jan	Lumee Oxygen Platform	20 Overig	Injecteerbare zuurstofsensor	12 Markttoelating	Three years after Profusa's biosensor earned the CE mark to measure tissue oxygen levels, its follow-up has followed suit. The latest EU clearance is for a wireless version of the device, which provides doctors a "broader data picture" and offers patients a more convenient way to check oxygen levels in their limbs. The Lumee Oxygen Platform is designed to monitor tissue at risk of low oxygen levels in patients with conditions like peripheral artery disease (PAD) and chronic limb ischemia.	https://www.fiercebiotech.com/medtech/profusa-s-wireless-injectable-oxygen-biosensor-nabs-ce-mark	
32	Klinische technologie	Risico	49	FDA warns of cybersecurity gaps in GE Healthcare's patient monitors	FierceBiotech	25-jan	GE Healthcare clinical information stations	07 Overig ICT	Cyberveiligheidsproblemen met bepaalde monitoren van GE.	06 Cybersecurity/hacken	he FDA has delivered a notice to healthcare providers and facilities warning them about cybersecurity vulnerabilities within certain clinical information stations made by GE Healthcare. These devices and telemetry serves are mainly used to monitor and display vital signs and patient information, including their heart rate, blood pressure and temperature. According to the agency, exploits have been uncovered that could allow attackers to remotely take control of the device, giving them the ability to silence alarms or generate false ones.	https://www.fiercebiotech.com/medtech/fda-warns-cybersecurity-gaps-ge-healthcare-s-patient-monitors	https://www.mddionline.com/ge-healthcare-devices-vulnerable-cyberattacks
32	Klinische technologie	Ontwikkeling	50	FDA approves Medtronic's tiny, wireless, minimally invasive pacemaker implant	FierceBiotech	23-jan	Micra AV	01 Actief implantaat	Nieuwe draadloze pacemaker van Medtronic	12 Markttoelating	The FDA approved a new, tiny pacemaker from Medtronic that does not require the wiring of separate electrodes between the implant and the heart. Less than one-tenth the size of traditional pacemakers and described as one of the world's smallest, the Micra AV device is designed to be placed entirely within the heart's right ventricle and attach itself to the muscle wall using small tines. The system is based on the medtech giant's previously approved Micra transcatheter pacing system for treating bradyarrhythmia. While identical in size and shape, the Micra AV is built for patients with atrioventricular block, which occurs when electrical signals from the heart's upper atria have trouble reaching its lower, pumping ventricles	https://www.fiercebiotech.com/medtech/fda-approves-medtronic-s-tiny-wireless-minimally-invasive-pacemaker-implant	https://www.mddionline.com/medtronics-tiny-pacemaker-now-fda-approved-av-block
32	Klinische technologie	Ontwikkeling	51	Microbot Medical unveils disposable device for remote catheter procedures	FierceBiotech	14-jan	Liberty robot	12 Operatie instrument	Robot om op afstand ingrepe met catheters uit te voeren	01 Nieuw product	SAN FRANCISCO—At the annual J.P. Morgan Healthcare Conference, Microbot Medical unveiled a new device that aims to let physicians conduct a catheter-based procedure from outside the operating room, sparing them from radiation exposure and physical stress. The Liberty robot straps to a patient's thigh and allows surgeons to advance and manipulate guidewires and microcatheters through the blood vessels via a handheld remote not unlike a video game controller. Additionally, the sterile robot's small size—and disposability, with a "one-and-done" design that can be mailed back to the manufacturer for recycling following each endovascular procedure—aims to cut back on hospitals' capital investments in robotic infrastructure.	https://www.fiercebiotech.com/medtech/jpm-microbot-medical-unveils-disposable-device-for-remote-catheter-procedures	
32	Klinische technologie	Risico	52	Medtronic warns spine surgeons its Mazor X robot could come loose and fall	FierceBiotech	8-jan	Mazor X robot	12 Operatie instrument	Mazor X robot voor rugoperaties kan loskomen van positie	03 Waarschuwing/incident	Medtronic alerted customers of its Mazor X robotic surgery system of its potential to come loose and detach itself from an operating room table, and possibly fall upon a patient during a spine procedure. The manufacturer has tracked the issue to the system's pneumatic positioning hardware, which lifts, mounts and locks the device to the OR bed frame. Over time, air leakage from certain models can weaken the system's grip, according to Medtronic.	https://www.fiercebiotech.com/medtech/medtronic-warns-spine-surgeons-its-mazor-x-surgery-robot-could-come-loose-and-fall	
32	Klinische technologie	Ontwikkeling	53	FDA clears PhotoniCare's handheld OCT scanner for checking ear infections	FierceBiotech	6-jan	TOMi scope	11 Beeldvormende/bestraling s technieken	FDA clears PhotoniCare's handheld OCT scanner for checking ear infections	12 Markttoelating	PhotoniCare received FDA 510(k) clearance for its hand-held, noninvasive imaging scope that allows physicians to check for fluids deep behind the eardrum—one of the main signs of childhood ear infections. The TOMi Scope diagnostic device uses optical coherence tomography, or OCT, to scan the middle ear with near-infrared light and provide a cross-section image similar to an ultrasound. It can then determine whether fluid is present and characterize its type and density, even in cases with heavy wax buildup.	https://www.fiercebiotech.com/medtech/fda-clears-photonicare-s-handheld-oct-scanner-for-checking-ear-infections	
32	Klinische technologie	Risico	54	Abbott's Coronary Dilation Catheters Face Class I Recall	MDDI	20-feb	NC Trek RX Coronary Dilatation Catheter	12 Operatie instrument	Recall van NC Trek RX Coronary Dilatation Catheter	03 Waarschuwing/incident	Abbott Laboratories is facing a Class I Recall of its coronary dilation catheters. The Abbott Park, IL-based company said that "certain lots" of the NC Trek RX Coronary Dilatation Catheter would be impacted by the recall. The "URGENT MEDICAL DEVICE RECALL" Notification informed customers that specific lots of its Coronary Dilatation Catheters with diameters of 4 mm, 4.5 mm, and 5 mm may exhibit difficulty or inability to deflate the balloon due to weaker material proximal to the balloon bond resulting from excess heat exposure during manufacturing, and the potential risks with the use of the affected products include air embolism, thrombosis, myocardial infarction, and additional intervention.	https://www.mddionline.com/abbott%E2%80%99s-coronary-dilation-catheters-face-class-i-recall	

32	Klinische technologie	Ontwikkeling	55	Dural Sealant Patch Made of Bioresorbable Polymers Earns CE Mark	MDDI	28-jan	Ligoseal patch	20 Overig	CE-markering voor afdichtingspatch voor de dura mater	01 Nieuw product	ligoseal, a dural sealant patch made of bioresorbable polymers, has received the CE mark and is now commercially available in Europe. Developed by Polyganics, the patch could help reduce cerebrospinal fluid (CSF) leakage after elective cranial surgery. CSF leakage is "a widely recognized complication of neurosurgical procedures that can result in increased morbidity, prolonged hospital stays, possible surgical revisions, and enhanced costs," Rudy Mareel, Polyganics's CEO, told MD+DI. "Incidence rates vary depending on age, indication, location of surgery and underlying pathology, but in total CSF leakage occurs in 4-32% of surgical cases."	https://www.mddionline.com/dural-sealant-patch-made-bioresorbable-polymers-earns-ce-mark	
32	Systeem	Ontwikkeling	56	New guidance published for Medical Device and IVD Cybersecurity under MDR and IVDR in Europe	Emergo	6-jan	Guidance on cybersecurity	16 Wet en regelgeving	Guidance on cybersecurity	05 Standaardisatie, wet-/regelgeving/NoBo	The Medical Device Coordination Group (MDCG) published new guidance on Jan 8, 2020 to help manufacturers fulfill all the relevant cybersecurity requirements in Annex I of the Medical Devices Regulation (MDR) and In-vitro Diagnostic Medical Devices Regulation (IVDR).	https://www.emergobyul.com/blog/2020/01/new-guidance-published-medical-device-and-ivd-cybersecurity-under-mdr-and-ivdr-europe	
32	Systeem	Ontwikkeling	57	European Commission issues new guidance on Eudamed medical device database nomenclature	Emergo	21-jan	Guidance on Eudamed medical device database nomenclature	17 Wet en regelgeving	Guidance on Eudamed medical device database nomenclature	6 Standaardisatie, wet-/regelgeving/NoBo	The European Commission has clarified requirements pertaining to nomenclature medical device manufacturers will use to enter their product information into the forthcoming Eudamed database. To this end, the EC has issued two recent guidance documents: One document covering the European Medical Device Nomenclature (EMDN), to be used by manufacturers once Eudamed goes fully online Another guidance provides background information on Italy's Classificazione Nazionale dei Dispositivi Medici (CND) nomenclature, whichwill be used as the basis for the EMDN	https://www.emergobyul.com/blog/2020/01/european-commission-issues-new-guidance-eudamed-medical-device-database-nomenclature	
32	Systeem	Ontwikkeling	58	State of play: European Commission provides latest figures on Notified Body MDR, IVDR designations	Emergo	28-jan	Update on notified bodies	18 Wet en regelgeving	Update on notified bodies	7 Standaardisatie, wet-/regelgeving/NoBo	According to an update from the European Commission, 44 applications from Notified Bodies for MDR designation have been submitted as of January 2020, four months before the Regulation's May 2020 application date. In addition, 11 applications for IVDR designation have been submitted so far, two years out from that Regulation's May 2022 compliance deadline. Although most Notified Bodies now designated to issue CE Marking under the European Medical Devices Directives have begun the work of obtaining designation under the MDR, the number of Notified Bodies actually designated to the Regulation and whose designation data has been entered into the European NANDO database has only recently climbed into the double digits: 12 official designations, plus nine NANDO entries as of January 21, 2020. (Three additional Notified Bodies' designation information is awaiting publication in NANDO, according to the EC report.)	https://www.emergobyul.com/blog/2020/01/state-play-european-commission-provides-latest-figures-notified-body-mdr-ivdr	
33	Systeem	Risico	59	'Ernst problemen failliete ziekenhuizen te laat erkend'	medisch contact	4-mrt	failliete ziekenhuizen	16 Wet en regelgeving	te late erkenning	06 Economisch nieuws	Het bankroet in 2018 van het MC Slotervaart in Amsterdam en de MC IJsselmeerziekenhuizen in Flevoland heeft een 'onacceptabele situatie' opgeleverd die in de toekomst voorkomen moet worden. 'Partijen zijn te laat geweest met het onderkennen van de ernst van de situatie en zijn te lang blijven hangen in hun eigen visie en rolopvatting', concluderen de onderzoekers. Ook extern, bij de gezondheidsinspectie, de Nederlandse Zorgautoriteit (NZa) en het ministerie van VWS, is te laat erkend dat het echt misging, zo is vastgesteld.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/ernst-problemen-failliete-ziekenhuizen-te-laat-erkend-.htm	
33	Medische hulpmiddelen	Risico	60	Vanaf donderdag 5 maart alleen nog spoedtandzorg bij ACTA door tekort mondneusmaskers	medicalfacts	4-mrt	tekort mondneusmaskers	20 Overig	tekort mondneusmaskers	03 Waarschuwing/incident	Door een landelijk tekort aan mondkapjes is ACTA (Academisch Centrum Tandheelkunde Amsterdam)gedwongen haar patiëntenzorg vanaf donderdag 5 maart aan te passen. Deze maatregel houdt in dat ACTA vanaf deze datum alleen nog spoedgevallen behandelt en lopende behandelingen kan afronden	https://www.medicalfacts.nl/2020/03/04/vanaf-donderdag-5-maart-alleen-nog-spoedtandzorg-bij-acta-door-tekort-mondneusmaskers/	
33	ICT, eHealth & Domotica	Risico	61	Datalek van van 4325 patiëntgegevens bij Flevoziekenhuis, patiënten geïnformeerd	medical facts	3-mrt	datalek	05 EPD/ patiëntgegevens	datalek	03 Waarschuwing/incident	Het Flevoziekenhuis heeft patiënten geïnformeerd over een datalek dat heeft plaatsgevonden. Een zorgverlener van het Flevoziekenhuis heeft ongeoorloofd patiëntgegevens op een USB-stick gezet. Deze USB-stick is verloren op een parkeerterrein nabij het Flevoziekenhuis. De USB-stick is door een gebruiker van het parkeerterrein op 9 oktober gevonden. De vinder heeft thuis de USB-stick even geopend en besloten deze terug te brengen naar het Flevoziekenhuis.	https://www.medicalfacts.nl/2020/03/03/datalek-van-van-4325-patientgegevens-bij-flevoziekenhuis-patienten-geinformeerd/	https://www.skipr.nl/nieuws/medewerker-flevoziekenhuis-lekt-gegevens-patienten-via-usb-stick/
33	Medische hulpmiddelen	Risico	62	Ministerie: snel plan voor voorraad medische beschermingsmiddelen	skipr	4-mrt	medische beschermingsmiddelen	20 Overig	tekort door coronavirus	03 Waarschuwing/incident	Het ministerie van Volksgezondheid wil zo snel mogelijk met een plan komen om tekorten aan medische beschermingsmiddelen, zoals mondkapjes, te voorkomen. Op het ministerie wordt woensdag overleg met onder meer leveranciers van beschermingsmiddelen, de GGD, zorgverzekeraars en ziekenhuizen. Er werd op het ministerie van VWS ook over medische hulpmiddelen in bredere zin gesproken, zoals wondgaas en chirurgische maskers. Veel van die spullen worden gemaakt in China, waardoor tekorten dreigen.	https://www.skipr.nl/nieuws/ministerie-snel-plan-voor-voorraad-medische-beschermingsmiddelen/	
33	Klinische technologie	Ontwikkeling	63	Elektronische neus spoort barrettslokdarm op	medisch contact	6-mrt	elektronische neus	20 Overig	elektroinsche neus diagnose barett slokdarm	01 Nieuw product	Het is mogelijk met behulp van een draagbare elektronische neus (een 'e-nose') een barrettslokdarm op te sporen. Dat blijkt uit een proof-of-principle-onderzoek door Yonne Peters e.a. (Radboudumc) gepubliceerd in Gut. Volgens onderzoeksleider en mdl-arts Peter Siersema zijn sensitiviteit en specificiteit vergelijkbaar met die bij borstkanker- en darmkankerscreening. Zijn verwachting is daarom dat op termijn deze goedkope en niet-invasieve techniek ingang zal vinden in de huisartsenpraktijk	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/elektronische-neus-spoort-barrettslokdarm-op.htm	
33	Systeem	Ontwikkeling	64	Tenzinger na overnames grootste ecd-leverancier in care	skipr	9-mrt	elektronisch clienten dossier	05 EPD/ patiëntgegevens	overname bedrijf	06 Economisch nieuws	ict-bedrijf Tenzinger neemt De Heer Software, leverancier van ECD Plancare, en de hieraan gelieerde e-healthleverancier Serviant over. Hiermee is het bedrijf naar eigen zeggen de grootste ecd-leverancier (elektronisch clienten dossier) in de markt voor gehandicapten-, ouderen- en thuiszorg.	https://www.skipr.nl/nieuws/tenzinger-na-overnames-grootste-ecd-leverancier-in-care/	

33	Medische hulpmiddelen	Risico	65	LHV en VPH: 'Tekort aan beschermingsmiddelen huisartsen nijpend'	medisch contact	16-mrt	medische beschermingsmiddelen	20 Overig	tekort door coronavirus	03 Waarschuwing/incident	De bodem van de voorraden persoonlijke beschermingsmiddelen van huisartsen tegen het SARS-CoV-2-virus, is nu echt bereikt, waarschuwt de Landelijke Huisartsen Vereniging (LHV). De huisartsenvereniging eist helderheid vanuit het ministerie van VWS over de vraag waarom de materialen de huisartsen niet bereiken. Een uiterst scenario wordt dat huisartsen tijdelijk geen zorg verlenen en mooten doorverwijzen naar andere praktijken en/of de GGD omdat een situatie zonder beschermingsmiddelen niet voort kan duren, stelt de LHV.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/lhv-en-vph-tekort-aan-beschermingsmiddelen-huisartsen-nijpend.htm	
33	ICT, eHealth & Domotica	Ontwikkeling	66	NZa versoepelt regels wegens extra coronakosten	medisch contact	16-mrt	digitale consulten	16 Wet en regelgeving	tijdelijke versoepeling regelgeving	05 Standaardisatie, wet-/regelgeving/NoBo	Alle face-to-faceconsulten in ziekenhuizen mogen per direct digitaal plaatsvinden. De Nederlandse Zorgautoriteit (NZa) versoepelt de regelgeving hiervoor tijdelijk vanwege de coronacrisis, zodat de kans op besmetting wordt verkleind en artsen deze digitale consulten vergoed krijgen.De regelgeving dicteert normaal dat er, voor het openen van een dbc aan het begin van een ziekenhuistraject, face-to-facecontact moet zijn tussen een patiënt en een zorgverlener die een dbc mag openen. De NZa laat weten die regelgeving dus voorlopig te verruimen, zodat alle eerste consulten digitaal mogen plaatsvinden en gedeclareerd kunnen worden.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/nza-versoepelt-regels-wegens-extra-coronakosten.htm	
33	In-vitro diagnostica	Risico	67	Waarschuwing over zelftesten voor coronavirus	igj	16-mrt	corona zelftest	08 POC test/zelftest	waarschuwing zelftest	03 Waarschuwing/incident	Testen die thuis gebruikt kunnen worden om na te gaan of je het coronavirus bij je draagt zijn verboden als ze niet eerst beoordeeld zijn door een aangemelde instantie. . Elke zelftest moet door een aangemelde instantie ('notified body') beoordeeld worden. De test moet een CE-markering dragen.	https://www.igj.nl/actueel/nieuws/2020/03/16/waarschuwing-over-zelftesten-voor-coronavirus	
33	Medische hulpmiddelen	Risico	68	Terugroepactie honderdduizenden mondkapjes in ziekenhuizen zijn onveilig	nu.nl	29-mrt	mondkapjes	20 Overig	onveilige mondkapjes	03 Waarschuwing/incident	Honderdduizenden mondmaskers die pas zijn geleverd aan Nederlandse ziekenhuizen, zijn ondougdelijk en kunnen niet worden gebruikt.Het ministerie van Volksgezondheid is een terugroepactie gestart. Het gaat om 600.000 zogeheten FFP2-maskers (mondkapjes met een filtertje) die niet aan de veiligheidseisen voldoen, bevestigt de woordvoerder. Volgens onderzoeksorganisatie TNO werken de filtertjes in de mondkapjes niet goed, of sluiten de mondkapjes niet genoeg aan op het gezicht, aldus de NOS.	https://www.nu.nl/coronavirus/6041045/terugroepactie-honderdduizenden-mondkapjes-in-ziekenhuizen-zijn-onveilig.html	
33	Klinische technologie	Ontwikkeling	69	3D-printers bieden hulp in coronacrisis	technischweekblad	19-mrt	onderdelen printen voor beademingsapparatuur	14 3D printer/product	onderdelen printen voor beademingsapparatuur	02 Nieuwe therapie/techniek	Vanwege de (dreigende) tekorten op het gebied van onder andere beademingsapparatuur door de coronacrisis schakelen niet-medische bedrijven over op de productie van essentiële onderdelen. 3D-printers spelen hierin een belangrijke rol. 3D-printen is duurder dan massaproductie en in het geval dan medische onderdelen is het belangrijk dat de producten aan alle medische eisen voldoen. Maar in geval van nood kunnen 3D-printers uitkomst bieden door snel en precies specialistische onderdelen te produceren.	https://www.technischweekblad.nl/nieuws/3d-printers-bieden-hulp-in-coronacrisis	
33	In-vitro diagnostica	Risico	70	Testcapaciteit coronavirus in gevaar door tekort aan laboratoriummateriaal	nos.nl	20-mrt	tekort aan benodigdheden	09 Diagnostische laboratorium testen	tekort aan benodigdheden	03 Waarschuwing/incident	Allerlei materialen die essentieel zijn om te kunnen vaststellen of iemand besmet is met het coronavirus zijn schaars. Er dreigen tekorten die de voortgang van de diagnostiek in gevaar brengen. In Nederland worden nu al relatief weinig mensen getest op het virus.	https://nos.nl/artikel/2327746-testcapaciteit-coronavirus-in-gevaar-door-tekort-aan-laboratoriummateriaal.html	
33	ICT, eHealth & Domotica	Ontwikkeling	71	CZ rolt app voor online huisartsenzorg versneld uit	ict&health	25-mrt	app online huisartenzorg	04 App	app online huisartenzorg	11 Overig	CZ heeft de afgelopen weken de ontwikkeling van de Medicoo app versneld. De app, die vanaf deze week (24 maart) beschikbaar is, is een van de oplossingen voor het huisartsentekort. Klanten van de zorgverzekeraar die geen eigen huisarts hebben kunnen via de Medicoo app een online huisarts raadplegen.	https://www.ichealth.nl/nieuws/cz-rolt-app-voor-online-huisartsenzorg-versneld-uit/	
33	Medische hulpmiddelen	Ontwikkeling	72	Mondkapjes herbruikbaar door sterilisatie	technisch weekblad	27-mrt	mondkapjes herbruikbaar	20 Overig	mondkapjes zijn te steriliseren	10 Nieuwe ontwikkeling	TU Delft en Van Straten Medical hebben een proces ontwikkeld en getest om mondkapjes zeker vijf keer te kunnen gebruiken. Het proces is direct en overal inzetbaar.	https://www.technischweekblad.nl/nieuws/mondkapjes-herbruikbaar-door-sterilisatie	https://www.delta.tudelft.nl/article/mondkapjes-herbruikbaar-door-
33	ICT, eHealth & Domotica	Ontwikkeling	73	Eerste patiënt behandeld met bestralingsplan van AI	technisch weekblad	26-mrt	bestralingsplan gemaakt dmv kunstmatige intelligentie	18 Artificial intelligence		10 Nieuwe ontwikkeling	Op 17 maart werd aan Amsterdam UMC de eerste patiënt met prostaatkanker behandeld op basis van een bestralingsplan ontwikkeld door kunstmatige intelligentie. De bestraling van tumoren bij prostaatkanker vindt aan Amsterdam UMC onder andere plaats middels brachytherapie. Hierbij wordt de patiënt inwendig bestraald, door een radioactieve bron te laten stralen in vooraf ingebrachte katheters.	https://www.technischweekblad.nl/nieuws/eerste-patient-behandeld-met-bestralingsplan-van-ai	
33	ICT, eHealth & Domotica	Risico	74	Kritische noten over onderzoek naar kunstmatige intelligentie	medisch contact	27-mrt	kunstmatige intelligentie	18 Artificial intelligence		03 Waarschuwing/incident	Het gebruik van kunstmatige intelligentie (artificial intelligence, AI) voor medische doeleinden wordt door velen bejubeld vanwege de ongekende mogelijkheden. Toch zijn er ook kanttekeningen te plaatsen omdat de daadwerkelijke prestaties van AI nogal eens worden overdreven in wetenschappelijke publicaties. Dit blijkt uit de resultaten van een systematic review door Myura Nagendran e.a. die is gepubliceerd in The BMJ.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/kritische-noten-over-onderzoek-naar-kunstmatige-intelligentie-.htm	
33	ICT, eHealth & Domotica	Ontwikkeling	75	CovApp geeft binnen vijf minuten een coronavirus indicatie	icthealth	27-mrt	CovApp	04 App		11 Overig	Sinds 2 maart is de CovApp in nederland actief is. Mensen beantwoorden via de app of de website van het ziekenhuis 26 eenvoudige vragen over zaken als reisactiviteit, leeftijd, beroep, symptomen of klachten etc. Alle informatie wordt geanonimiseerd opgeslagen en er worden geen persoonlijke of privacy-gevoelige gegevens gedeeld met het ziekenhuis.Het invullen duurt zo'n 5 minuten en vervolgens geeft CovApp direct de uitslag. Dat kunnen ook aanbevelingen zijn voor mogelijke vervolgacties. Denk aan het advies om contact op te nemen met een arts of om 14 dagen in thuisquarantaine te gaan. De uitslag bevat ook een QR-code die, indien nodig, naar een arts of ziekenhuis gestuurd kan worden zodat die zich kunnen voorbereiden op de komst van een patiënt.	https://www.ichealth.nl/nieuws/covapp-geeft-binnen-vijf-minuten-een-coronavirus-indicatie/	
33	ICT, eHealth & Domotica	Ontwikkeling	76	Meldpunt voor zorgmedewerkers om tekort aan beschermende middelen	nos.nl	30-mrt	meldpunt	07 Overig ICT		11 Overig	Er is een meldpunt geopend voor zorgmedewerkers om het tekort aan beschermende middelen in kaart te brengen. Het initiatief komt van NU'91, de beroepsvereniging voor verpleegkundigen en verzorgenden. Vanuit het hele land komen signalen binnen bij NU'91 dat er bijvoorbeeld onvoldoende mondmaskers zijn ter bescherming tegen het coronavirus.	https://nos.nl/artikel/2328795-meldpunt-voor-zorgmedewerkers-om-tekort-aan-beschermende-middelen.html	

33	Medische hulpmiddelen	Risico	77	Mondkapjes redden van de afvalhoop in strijd tegen Coronatekorten	fmt gezondheidszorg	2-apr	mondkapjes	20 Overig	tekorten	03 Waarschuwing/incident	In samenwerking met de TU Delft, Franciscus Gasthuis, Reinier de Graaf Ziekenhuis en na overleg met verschillende ziekenhuizen en Deskundigen Steriele Medische Hulpmiddelen is een methode getest om gebruikte mondkapjes te steriliseren via een generiek sterilisatieproces. De testresultaten komen overeen met de resultaten van nieuwe mondkapjes.	https://fmtgezondheidszorg.nl/mondkapjes-redden-van-de-afvalhoop-in-strijd-tegen-coronatekorten/	
33	ICT, eHealth & Domotica	Ontwikkeling	78	Nederlandse bedrijven bieden COVID-19 AI-software gratis aan	fmt gezondheidszorg	2-apr	AI gratis	18 Artificial intelligence	gratis in coronacrisis tijd	11 Overig	Thirona en Delft Imaging lanceren CAD4COVID. Deze nieuwe tool voor kunstmatige intelligentie analyseert röntgenfoto's en is bedoeld om zorgspecialisten te helpen bij het beheren van COVID-19-gevallen. De bedrijven hebben de tool gratis ter beschikking gesteld ter ondersteuning van de crisis.	https://fmtgezondheidszorg.nl/nederlandse-bedrijven-bieden-covid-19-ai-software-gratis-aan/	
33	ICT, eHealth & Domotica	Ontwikkeling	79	Google en Apple bouwen 'corona-tracking' in op smartphones	nos.nl	10-apr	tracking app	04 App	corona tracking app	11 Overig	Google en Apple gaan een samenwerking aan om overheden te helpen bij corona-onderzoek. Dat moet een einde maken aan technische problemen bij de ontwikkeling van de 'corona-apps' die overheden willen gaan inzetten.	https://nos.nl/artikel/2330078-google-en-apple-bouwen-corona-tracking-in-op-smartphones.html	
33	ICT, eHealth & Domotica	Ontwikkeling	80	Lancering landelijk online portaal voor het digitaal uitwisselen van relevante COVID-19 patiëntgegevens tussen ziekenhuizen	fmt gezondheidszorg	16-apr	digitaal uitwisselen covid-19	07 Overig ICT	digitaal uitwisselen covid-19	11 Overig	Philips maakt in nauwe samenwerking met het ministerie van Volksgezondheid, Welzijn en Sport en het Erasmus Medisch Centrum het online COVID-19 portaal beschikbaar waarmee Nederlandse ziekenhuizen patiëntinformatie met elkaar kunnen delen als patiënten verplaatst worden naar een ander ziekenhuis wegens COVID-19. Via het portaal kunnen radiologische beelden, verslagen, documenten (bijv. de ontslagbrief) en andere relevante informatie over een patiënt beschikbaar gemaakt worden voor het ontvangende ziekenhuis. Hiermee kan de spreiding van COVID-19 patiënten over Nederland worden ondersteund.	https://fmtgezondheidszorg.nl/lancering-landelijk-online-portaal-voor-het-digitaal-uitwisselen-van-relevante-covid-19-patientgegevens-tussen-ziekenhuizen/	
33	ICT, eHealth & Domotica	Ontwikkeling	81	Kabinet gaat werken aan nieuwe corona-app	icthealth	22-apr	corona-app	04 App	corona-app	01 Nieuw product	Het kabinet laat een nieuwe corona-app ontwikkelen om coronabesmettingen in kaart te brengen. Dat geeft minister Hugo de Jonge van VWS aan de Tweede Kamer aan. De zeven tracking-apps die afgelopen weekeinde tijdens een appathon waren geselecteerd, vallen af. Over vier weken moet meer duidelijk zijn over of en zo ja, hoe apps ingezet kunnen worden.	https://www.icthealth.nl/nieuws/kabinet-komt-uiterlijk-19-mei-met-nieuwe-corona-app/	https://nos.nl/artikel/2331304-minister-de-jonge-stelt-team-samen-om-zelf-app-te-bouwen.html
33	Medische hulpmiddelen	Ontwikkeling	82	Scholier helpt ziekenhuis met slimmigheidje voor mondkapjes	rtl nieuws	16-apr	hulpstuk voor mondkap	14 3D printer/product	hulpstuk voor mondkap	01 Nieuw product	scholier maakt middels 3d-printer een hulpstuk voor mondkapjes zodat deze beter en passender zitten.	https://www.youtube.com/watch?v=-gA9VtlzFgU	
33	Klinische technologie	Ontwikkeling	83	Open source beademingsapparaat na test snel inzetbaar	icthealth	17-apr	Open source beademingsapparaat	20 Overig	Open source beademingsapparaat na test snel inzetbaar	10 Nieuwe ontwikkeling	Enkele weken geleden verscheen het nieuws over een in ontwikkeling zijnd open source beademingsapparaat, de VentilatorPAL. De professionele variant daarvan, de VentilatorPAL Pro, is inmiddels met succes getest door specialisten van de Universiteit Twente, Radboudumc en de fabrikant, FreeBreathing. Dit betekent dat het betaalbare en snel ontwikkelde beademingsapparaat op korte termijn ingezet kan worden.	https://www.icthealth.nl/nieuws/open-source-beademingsapparaat-na-test-inzetbaar/	
33	Implantaten	Ontwikkeling	84	Abbott's FlexNav Cleared in EU to Deliver Portico Transcatheter Aortic Valve	medgadget	6-mrt	Applicator voor Transcatheter aortaklep vervanging	12 Operatie instrument	markttoelating applicator TAV	12 Markttoelating	Abbott announced that it received the EU CE Mark for the new FlexNav delivery system for the company's Portico transcatheter aortic valve. The FlexNav delivery system gives physicians more stability, predictability and placement accuracy during the TAVI procedure. While valve technology improvements have helped reduce adverse events and lead to better patient outcomes, advancements to delivery systems are critical to improving the placement and positioning of the valve, according to the announcement.	https://www.medgadget.com/2020/03/abbott-receives-ce-mark-for-flexnav-delivery-system-for-transcatheter-aortic-valve-implantation.html	https://cardiovascularnews.com/abbott-receives-ce-mark-for-flexnav-delivery-system/
33	Medische hulpmiddelen	Ontwikkeling	85	Tivic Wins EU Clearance for ClearUP Sinus Relief Device	Medgadget	9-mrt	Ticic ClearUP Sinus Relief Device	20 Overig	ce markering device om met zenuwstimulatie klachten van verstopte sinussen te verlichten	12 Markttoelating	San Francisco-based Tivic Health announced that the company has received CE Mark approval in Europe for ClearUP Sinus Pain Relief, a small handheld device that can temporarily relieve allergy-related sinus pain, pressure, and congestion. ClearUP is a small handheld device that delivers a proprietary microcurrent waveform that stimulates sinus nerve fibers under the skin to relieve pain related to allergies. It is designed to treat symptoms in five minutes and can be used up to four times per day. ClearUP employs a light and vibration system to guide the user along the most optimal treatment points along the cheek, nasal bone, and brow bone. There is a one-button control with three levels of waveform intensity, and symptomatic relief lasts up to six hours.	https://www.medgadget.com/2020/03/tivic-wins-eu-clearance-for-clearup-sinus-relief-device.html	
33	Implantaten	Ontwikkeling	86	V-Wave Shunt for Relief of Heart Failure Symptoms Cleared in EU	Medgadget	9-mrt	V-Wave Ventura	02 Niet actief implantaat	ce-markering voor interatrium shunt klep	12 Markttoelating	Heart failure patients often suffer from high pressure within the left side of their hearts, which can lead to difficulties breathing and other debilitating conditions. V-Wave, an Israeli firm, won the European CE Mark of approval for its Ventura interatrial shunt that aims to regulate left atrial pressure by creating a passage for blood to flow from the left to the right atrium across the interatrial septum. The device is implanted during a minimally invasive transcatheter procedure and once there, it allows some blood to flow from the left to the right side of the heart, thereby lowering the pressure and impact of fluid buildup within the lungs.	https://www.medgadget.com/2020/03/v-wave-shunt-for-relief-of-heart-failure-symptoms-cleared-in-eu.html	
33	ICT, eHealth & Domotica	Ontwikkeling	87	Symmetry VNS Wins EU CE Mark for Difficult-to-Treat Depression	Medgadget	10-mrt	nervusvagus stimulator Livanova Symmetry	01 Actief implantaat	ce-markering voor neurostimulator om depressie te behandelen	12 Markttoelating	LivaNova announced today that Symmetry, a device for vagus nerve stimulation (VNS) therapy, has received CE Mark approval for difficult-to-treat depression. Symmetry is a small device that stimulates the vagus nerve to improve symptoms of depression and quality of life. After surgical implantation, the device regularly sends mild electric pulses to the vagus nerve, which is connected to areas of the brain that control mood. While previous devices for VNS therapy have received CE Mark for the treatment of depression, Symmetry is the newest and is specifically designed for this indication.	https://www.medgadget.com/2020/03/symmetry-vns-wins-eu-ce-mark-for-difficult-to-treat-depression.html	

33	ICT, eHealth & Domotica	Ontwikkeling	88	EchoNous Receives EU Approval for Kosmos AI Ultrasound Platform	Medgadget	23-mrt	Echonous Kosmos AI	18 Artificial intelligence	CE-markering echosysteem met AI hulp	12 Markttoelating	EchoNous announced that it has received the European CE Mark of approval for its Kosmos platform, an ultrasound and AI-based software system that helps physicians obtain diagnostic imaging and make clinical decisions at the bedside. The Kosmos platform consists of an eight-ounce ultrasound device, the Kosmos Torso, which also has ECG and digital auscultation functions. It is connected to the Kosmos Bridge tablet, which runs AI-based software that analyzes the ultrasound images to assess heart and lung function more quickly and accurately.	https://www.medgadget.com/2020/03/echonous-receives-eu-approval-for-kosmos-ai-ultrasound-platform.html	
33	Klinische technologie	Ontwikkeling	89	MIT Engineers Working to Submit Emergency Ventilator for FDA Review	Medgadget	24-mrt	Beademingsapperaat	20 Overig	Ontwikkeling beademingssysteem voor COVID-19 patienten	01 Nieuw product	The ongoing COVID-19 emergency affecting nearly the entire globe is making medical ventilators into a hot commodity. During normal times, busy intensive care units can expect to use a dozen or so ventilators at the same time. As a respiratory virus, COVID-19 can make breathing on one's own impossible, so ventilators are expected to be in dire shortage almost everywhere. A group of MIT engineers are working to submit a variant of the MIT E-Vent design to the FDA, under Emergency Use Authorization (EUA), a ventilator made out of a bag valve mask (aka Ambu-Bags) and readily available electronics, actuators, and motors. Bag valve masks are themselves found near every hospital bed in case emergency oxygenation is necessary, so they should be in sufficient supply already.	https://www.medgadget.com/2020/03/mit-emergency-ventilator-submitted-for-fda-review.html	
33	Medische hulpmiddelen	Ontwikkeling	90	ProtectivAir Sterilizes Inhaled Air Using UV Light	Medgadget	27-mrt	ProtectivAir lucht sterilisator	20 Overig	UV sterilisator van ingeademende lucht ter voorkoming besmetting	01 Nieuw product	Medi-Immune, a UK firm, recently revealed ProtectivAir, a breathing device that uses UVc light to sterilize inhaled air and protect wearers against airborne pathogens, potentially including SARS-CoV-2 (COVID-19). The device is meant to be used by healthcare staff and others with occupational exposure to airborne pathogens. ProtectivAir consists of a nose and mouth mask that connects, via a flexible hose, to a small irradiation chamber worn on a belt or harness. The irradiation chamber uses UVc photons to disinfect inhaled air. UVc damages a pathogen's DNA or RNA, which prevents it from replicating and infecting the body.	https://www.medgadget.com/2020/03/protectivair-sterilizes-inhaled-air-using-uv-light.html	
33	Medische hulpmiddelen	Ontwikkeling	91	New Device to Disinfect 500 N95 Masks Per Hour	Medgadget	30-mrt	Prescientx Terminator n95 sterilisator	20 Overig	UV-Sterilisator voor grote aantallen n95 maskers	01 Nieuw product	Prescientx, an Ontario, Canada firm, has just started taking orders for a device that can rapidly disinfect N95 masks using ultraviolet (UV) light. By bathing the masks with light in the UV-C range, the Terminator CoV device can process up to 500 masks per hour. This is quite spectacular, given the current shortage of masks, and should be enough to keep most clinical facilities from running out of masks during our current pandemic.	https://www.medgadget.com/2020/03/new-device-to-disinfect-500-n95-masks-per-hour.html	
33	Medische hulpmiddelen	Ontwikkeling	92	STERRAD Sterilizers Triple Lifetime of N95 Masks	Medgadget	30-mrt	Sterilisator N95 maskers	20 Overig	Sterilisator stelt in staat om N95 maskers tot 2 keer hertegebruiken	11 Overig	STERRAD sterilizers, made by Advanced Sterilization Products (ASP), an Irvine, California firm, are a common sight in hospitals around the world. They're used to reprocess surgical tools and other equipment, but now the same devices can be immediately utilized to turn single-use N95 masks into reusable devices. ASP has just qualified a new reprocessing protocol that can add two extra uses to common N95 masks, tripling their useful lifetime. Already installed STERRAD systems can be easily implemented to process the masks, and ASP claims that a single STERRAD setup can reprocess 480 masks per day.	https://www.medgadget.com/2020/03/sterrad-sterilizers-triple-lifetime-of-n95-masks.html	
33	Klinische technologie	Ontwikkeling	93	CardioQuip's Cooler-Heaters EU Cleared to Help With Respiratory Distress	medgadget	1-apr	Regulator lichaamstemperatuur	20 Overig	Ce-markering device om lichaamstemperatuur te reguleren tijdens ECMO	12 Markttoelating	CardioQuip, a firm based in College Station, Texas, won European regulatory approval (CE Mark) for its MCH-1000 cooler-heaters that are used to control patient body temperature, typically during lung or heart procedures. This could be particularly useful during the current COVID-19 pandemic, since the MCH-1000 can be used alongside extracorporeal membrane oxygenation (ECMO) to address acute respiratory distress. "Landing the CE Mark is a tremendous milestone for CardioQuip," said Doug Platt, CEO of the company. "The approval allows us to offer our technology to major hospitals all over the European Union (EU) at a time when it is greatly needed. We are excited to be in the final stages of agreements with European distribution partners to aide our commercialization efforts and get the MCH-1000 to the EU as quickly as possible."	https://www.medgadget.com/2020/04/cardioquips-cooler-heaters-eu-cleared-to-help-with-respiratory-distress.html	
33	Klinische technologie	Ontwikkeling	94	Next-Gen TherOx SuperSaturated Oxygen Delivery System FDA Approved	medgadget	1-apr	Supergesatureerde zuurstof toediener	20 Overig	Fda-goedkeuring	12 Markttoelating	ZOLL Medical, now a part of Asahi Kasei Group, won FDA approval for the latest version of its TherOx System. The product is designed to deliver SuperSaturated Oxygen (SSO2) therapy to limit heart muscle loss following "widowmaker" heart attacks, aka left anterior descending ST-elevation myocardial infarction (LAD STEMI) chronic total obstruction. The system is used right after blood flow is restored during angioplasty and stent implantation to pump hyperbaric levels of oxygen straight into injured cardiac tissue. It's important that this happens within six hours of the onset of symptoms.	https://www.medgadget.com/2020/04/next-gen-therox-supersaturated-oxygen-delivery-system-fda-approved.html	
33	Klinische technologie	Ontwikkeling	95	AnapnoGuard Helps Prevent Ventilator Complications	medgadget	1-apr	Device om afsluiting van endotracheale cuff te waarborgen tijdens beademing	20 Overig	CE en FDA goedkeuring	12 Markttoelating	Ventilators are important to maintain patients with severe respiratory distress due to COVID-19, but the machines carry their own risks. An over-inflated endotracheal tube cuff could damage the trachea, while an under-inflated cuff could result in aspiration and pneumonia. AnapnoGuard, developed by Hospitech Respiration, an Israeli firm, is an endotracheal tube plus control unit meant to be used with ventilators to prevent complications of both over- and under-inflation. The company has announced that it will provide its AnapnoGuard device to Israeli hospitals free of charge.	https://www.medgadget.com/2020/04/anapnoguard-helps-prevent-ventilator-complications.html	

33	In-vitro diagnostica	Ontwikkeling	96	Ortho Diagnostics Unveils COVID-19 Antibody Test	medgadget	6-apr	COVID-19 antilichaam test	09 Diagnostische laboratorium testen	IVD voor antilichamen COVID-19	01 Nieuw product	Ortho Clinical Diagnostics, a company out of Raritan, New Jersey, has unveiled its SARS-CoV-2 (COVID-19) antibody test, a development that may allow the detection of those who have already fought off the virus, but never knew they had it. This will help with tracking the spread of COVID-19, identify clinical staff that can pretty safely inhabit the space of current COVID-19 patients, and significantly expand the study of the virus. Currently, the viral spread and level of public immunity to the virus is unknown, as the number of those who have fought off the virus is unknown. The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack, as the test is known, spots antibodies (including IgG and IgM) that are produced in response to COVID-19 and so can predict how the individual's immune system will respond to exposure to the virus.	https://www.medgadget.com/2020/04/ortho-diagnostics-unveils-covid-19-antibody-test.html	
33	Implantaten	Ontwikkeling	97	Abbott TriClip Cleared in Europe for Minimally Invasive Tricuspid Valve Repair	medgadget	13-apr	Device voor transcatheter reparatie van triscupidalis-klep	12 Operatie instrument	Ce markering	12 Markttoelating	Abbott announced that it received the European CE Mark for its TriClip Transcatheter Tricuspid Valve Repair System, a minimally-invasive device for tricuspid regurgitation repair. Like many other valve repair devices, TriClip is designed for implantation using a minimally-invasive transcatheter procedure. Unlike other devices, however, TriClip works by clipping together a portion of the leaflets that make up the tricuspid valve. This recuces the backflow of blood in tricuspid regurgitation patients that is responsible for clinical symptoms and long-term cardiac sequela. TriClip is available in two different sizes.	https://www.medgadget.com/2020/04/abbott-triclip-cleared-in-europe-for-minimally-invasive-tricuspid-valve-repair.html	
33	Klinische technologie	Ontwikkeling	98	Blood Filtering Device Wins FDA Emergency Use Authorization for COVID-19	medgadget	13-apr	Cytokine filter device voor COVID-19 patienten	20 Overig	FDA emergency use toelating	12 Markttoelating	The device is intended to lower the levels of cytokines and other proteins in blood that promote inflammation, hopefully thereby mitigating some of the terrible consequences of the infection. These can include shock, lung failure, other organ failure and result in death. The FDA has issued the first Emergency Use Authorization for a device to help treat COVID-19 patients currently in the ICU. Terumo BCT's Spectra Optia Apheresis System, combined with Marker Therapeutics' D2000 Adsorption Cartridge, is now indicated for adult patients with COVID-19 undergoing respiratory failure.	https://www.medgadget.com/2020/04/blood-filtering-device-wins-fda-emergency-use-authorization-for-covid-19.html	
33	Klinische technologie	Ontwikkeling	99	TransAeris Diaphragm Pacing System Gets FDA Emergency Use Authorization for Quicker Ventilator Weaning	medgadget	16-apr	Diafragma stimulator	20 Overig	FDA emergency use toelating	12 Markttoelating	As hospitals face the possibility of ventilator shortages for COVID-19 patients, Synapse Biomedical announced that it received FDA Emergency Use Authorization for a device that helps wean patients off ventilators quicker. This, in turn, could free up ventilators for use by other patients. Weaning off of mechanical ventilation is a constant challenge in intensive care units, as prolonged ventilation can lead to diaphragm disuse atrophy and ventilator-induced diaphragmatic dysfunction (VIDD). VIDD makes it harder for patients to return to breathing on their own and increases ventilation time.	https://www.medgadget.com/2020/04/transaeris-diaphragm-pacing-system-gets-fda-emergency-use-authorization-for-quicker-ventilator-weaning.html	
33	In-vitro diagnostica	Ontwikkeling	100	CRISPR-Based Test to Diagnose COVID-19 in Less than One Hour	medgadget	17-apr	COVID-19 test met CRISPR techniek	09 Diagnostische laboratorium testen	Ontwikkeling labtest om COVID-19 te diagnosticeren	02 Nieuwe therapie/techniek	With the COVID-19 pandemic growing globally, new ways of detecting the infection is the need of the hour. University of California, San Francisco researchers have recently published a paper in Nature Biotechnology outlining their approach to diagnose COVID-19 infections from respiratory swabs using CRISPR. The test, called the SARS-CoV2 DETECTR assay, checks for the presence of two specific regions in the novel coronavirus – one is found in all 'SARS-like' coronaviruses and one is unique to SARS-CoV-2, which causes COVID-19. This helps to differentiate COVID-19 infections from similar infections caused by other coronaviruses	https://www.medgadget.com/2020/04/crispr-based-test-to-diagnose-covid-19-in-less-than-one-hour.html	
33	Medische hulpmiddelen	Ontwikkeling	101	Ultraviolet System to Sterilize Thousands of Masks Per Day	medgadget	23-apr	Uv-sterilisator	20 Overig	Sterilisator stelt in staat om N95 maskers in grote aantallen steriliseren	01 Nieuw product	Ultraviolet light, particularly in the UVC range (280–100 nm), is known to inactivate microbes. During the current COVID-19 pandemic there's a shortage of protective masks, particularly N95 masks that feature electrostatic filters. Cleaning such masks using liquids is not effective, as the electrostatic effect ends up neutralized, so a team at Rensselaer University created a device that bathes masks in UVC light and makes them useful again. Inside the irradiation box are two UVC bulbs that stretch horizontally across the chamber. A motorized conveyor pulls masks, which are hung at one end of the box, in between the bulbs. The speed of the motor can be controlled to choose the desired amount of radiation exposure for the masks and to prevent over-exposure that can actually damage the structural integrity of the mask.	https://www.medgadget.com/2020/04/ultraviolet-system-to-sterilize-thousands-of-masks-per-day.html	
33	In-vitro diagnostica	Ontwikkeling	102	Graphene Biosensor Developed for Rapid COVID-19 Testing	medgadget	29-apr	Biosensor obv grafeen om COVID-19 te diagnosticeren	09 Diagnostische laboratorium testen	Nieuwe techniek om COVID-19 te diagnosticeren met lab test	02 Nieuwe therapie/techniek	Researchers at the Korea Basic Science Institute, Korea Research Institute of Chemical Technology, and collaborators have published an article on the development of graphene-based test for SARS-CoV-2, the virus causing COVID-19, from nasopharyngeal swabs. They have determined it can detect SARS-CoV-2 in clinical samples at a concentration of 242 copies per mL and greater, a significant achievement. Current diagnostic tests for COVID-19 utilize RT-PCR, amplifying the SARS-CoV-2 RNA from patient samples so tiny amounts of virus can be detected. It takes at least 3 hours, including methods for RNA preparation. The researchers who initiated this new study wanted to develop a faster test directly from patient swabs, without sample preparation steps.	https://www.medgadget.com/2020/04/graphene-biosensor-developed-for-rapid-covd-19-testing.html	

33	In-vitro diagnostica	Ontwikkeling	103	Sensitive 10 Minute Antibody Test for SARS-CoV-2 Developed	medgadget	30-apr	Antilichaam test COVID-19	08 POC test/zelftest	Nieuwe techniek om COVID-19 te diagnosticeren met zelftest	02 Nieuwe therapie/techniek	A team of researchers at the Southern Medical University, Guangzhou, China, and collaborators report development of a rapid diagnostic assay for detection of SARS-CoV-2 antibodies in human blood. They report accurate detection with patient samples, with only 10 minutes to get a readout per blood sample. The new method is a lateral flow assay, much like a home pregnancy test. Human serum is obtained from a test patient and added onto one side of the device, where it flows through the paper due to capillary action. The researchers impregnated COVID-19 proteins in a thin line on this paper to bind the antibodies. If the anti-COVID-19 antibodies are present, they will bind along this line, else, there will be no binding activity. To improve resolution, the researchers also use secondary binding of rabbit anti-human IgG antibodies, linked with a fluorescent reporter, allowing for greater accuracy than an unassisted visual readout.	https://www.medgadget.com/2020/04/sensitive-10-minute-antibody-test-for-sars-cov-2-developed.html	
33	Systeem	Ontwikkeling	104	COVID-19: European Commission looking to postpone new MDR by one year	Cardiac Rhythm News	27-mrt	Medical Device Regulation	16 Wet en regelgeving	opschorten Verordering Medische Hulpmiddelen	05 Standaardisatie, wet-/regelgeving/NoBo	During a Q&A section of a European Commission (EC) college meeting on 25 March, EC spokesperson Stefan de Keersmaecker stated that the commission were looking to delay the "entry into force" of the new European medical device regulations (MDR) because of the global coronavirus pandemic.	https://cardiacrhythmnews.com/covid-19-european-commission-looking-to-postpone-new-mdr-by-one-year/	https://www.emergobyul.com/blog/2020/03/european-commission-proposes-one-year-delay-medical-devices-regulation?utm_source=
33	Systeem	Ontwikkeling	105	COVID-19: European Commission agrees to postpone new MDR because of pandemic	Cardiac Rhythm News	6-apr	Medical Device Regulation	16 Wet en regelgeving	opschorten Verordering Medische Hulpmiddelen	05 Standaardisatie, wet-/regelgeving/NoBo	The European Commission (EC) has adopted a proposal to postpone by one year the date of application of the new Medical Devices Regulation (MDR), which was due to come into force on 26 May this year. The postponement, a press release reports, is to allow Member States, health institutions and economic operators to prioritise "the fight against the coronavirus pandemic". As previously reported, the announcement follows the EC college (video) meeting on 25 March in which EC spokesperson Stefan de Keersmaecker stated that the commission were looking to delay the "entry into force" of the new MDR because of the global coronavirus pandemic.	https://cardiacrhythmnews.com/covid-19-european-commission-agrees-to-postpone-new-mdr-because-of-pandemic/	https://www.emergobyul.com/blog/2020/04/european-commission-officially-proposes-one-year-mdr-delay?utm_source=RADAR&utm_medium=Email&utm_campaign=Email-RADAR https://evtoday.com/new
33	Systeem	Ontwikkeling	106	COVID-19 in Europe: Postponed and remote Notified Body audits for medical device manufacturers	Emergo	14-apr	notified body audits	16 Wet en regelgeving	guidance for postponed or remote notified body audits	05 Standaardisatie, wet-/regelgeving/NoBo	New guidance from the European Commission's Medical Device Coordination Group (MDCG) temporarily makes allowances for postponed or remote audits of medical device manufacturers necessary for recertification of CE Marking and related requirements.	https://www.emergobyul.com/blog/2020/04/covid-19-europe-postponed-and-remote-notified-body-audits-medical-device-manufacturers	
33	Systeem	Ontwikkeling	107	European Parliament officially supports postponing MDR date of application	Emergo	22-apr	Medical Device Regulation	16 Wet en regelgeving	opschorten Verordering Medische Hulpmiddelen	05 Standaardisatie, wet-/regelgeving/NoBo	In a widely anticipated move, the European Parliament has adopted the European Commission's proposal to postpone the Medical Devices Regulation's date of application by one year as healthcare regulators, governments and industry grapple with the COVID-19 emergency.	https://www.emergobyul.com/blog/2020/04/european-parliament-officially-supports-postponing-mdr-date-application	
33	Klinische technologie	Risico	108	Is laparoscopisch opereren veilig ten tijde van de COVID-19 pandemie?	Mtintegraal	20-apr	laparascopie	13 Scopen & camera's	veilgheid laparoscopisch opereren	11 Overig	Sinds de uitbraak van de COVID-19 pandemie is veel gezegd en geschreven over de wijze waarop het virus zich verspreidt. Dit heeft reeds grote gevolgen gehad voor de wijze waarop de dagelijkse zorg wordt ingericht. Desondanks komt dagelijks nieuwe informatie beschikbaar en ontstaan met eenzelfde snelheid nieuwe vragen. Eén van de vragen is of laparoscopisch opereren momenteel veilig is.	https://mtintegraal.nl/artikelen/978/is-laparoscopisch-opereren-veilig-ten-tijde-van-de-covid-19-pandemie	
33	In-vitro diagnostica	Ontwikkeling	109	Smartphone-based multiplex 30-minute nucleic acid test of live virus from nasal swab extract	Lab on a chip	25-apr	Smartphone-based IVD	08 POC test/zelftest	Smartphone-based IVD	10 Nieuwe ontwikkeling	Rapid, sensitive and specific detection and reporting of infectious pathogens is important for patient management and epidemic surveillance. We demonstrated a point-of-care system integrated with a smartphone for detecting live virus from nasal swab media, using a panel of equine respiratory infectious diseases as a model system for corresponding human diseases such as COVID-19. Specific nucleic acid sequences of five pathogens were amplified by loop-mediated isothermal amplification on a microfluidic chip and detected at the end of reactions by the smartphone. Pathogen-soiled horse nasal swab samples were correctly diagnosed using our system, with a limit of detection comparable to that of the traditional lab-based test, polymerase chain reaction, with results achieved in 30 minutes.	https://pubs.rsc.org/en/content/articlelanding/2020/LC/D0LC00304B#!divAbstract	
33	Implantaten	Risico	110	Could Your E-Cig Disrupt Your Pacemaker?	MedicineNet	16-mrt	pacemakers en defibrillatoren	01 Actief implantaat	interferentie actief hart implantaat en e-sigaret	11 Overig	The magnets in vaping devices might be able to wreak havoc on heart pacemakers and defibrillators, a new case report suggests	https://www.medicinenet.com/script/main/art.asp?articlekey=228884	
33	Medische hulpmiddelen	Risico	111	FDA warns of premature EpiPen auto-injector activations	FierceBiotech	25-mrt	EpiPen	20 Overig	Voortijdige activatie auto-injector	03 Waarschuwing/incident	The FDA warned patients, parents and providers that various EpiPen models could malfunction and spring their needles early. This could happen spontaneously if certain pressures are applied while removing the blue safety release on the rear of the epinephrine auto-injector. For example, the device could activate if the release is forced sideways—such as if a person is holding the EpiPen with one hand and uses their thumb to push off the safety cap. Additionally, the FDA described a limited number of EpiPens that may have been shipped with a slightly raised or loosened blue safety release, which may also allow the injector to activate prematurely. The agency recommended that users activate the device by pulling the cap straight up while holding the EpiPen in the other hand.	https://www.fiercebiotech.com/medtech/fda-warns-premature-epipen-auto-injector-activations	

33	Medische hulpmiddelen	Ontwikkeling	112	French startup Dianosic nets CE mark for nosebleed-stopping balloon	FierceBiotech	16-mrt	CAVI-T device	20 Overig	Ballon voor stoppen bloedneus	01 Nieuw product	A French startup has received a CE mark for a small, inflatable device designed to apply gentle pressure and halt nosebleeds. The Strasbourg-based Dianosic plans to eventually make its blodstopping balloon available in hospitals throughout Europe, the U.S., Japan and China. After being inserted into the nostril, the company's CAVI-T device expands to conform to the shape of the cavity and provide light amounts of compression to help stop the bleeding, inclucing at the front or back of the airway. It can be used for spontaneous bleeds or left in place for up to three days in more serious cases, including after operations such as sinus surgeries or rhinoplasties.	https://www.fiercebiotech.com/medtech/french-startup-dianosic-nets-ce-mark-for-nosebleed-stopping-balloon	
33	Klinische technologie	Risico	113	FDA designates BD's wide-ranging Alaris infusion pump recall as Class I	FierceBiotech	9-mrt	Alaris infusion pump	20 Overig	Recall infuuspompen en monitors	03 Waarschuwing/incident	BD is recalling hundreds of thousands of its Alaris infusion pumps and vital sign monitors due to multiple system faults, including software- and user-related issues. According to the FDA, the errors can lead to delays or interruptions in drug infusions or under- or over-dosing of medication at unexpected rates. The agency categorized the recall as Class I, its most serious, following 55 reported injuries and one death. The recall affects about 774,000 devices in the U.S., distributed from as early as July 2004. This includes system PCs, pump modules and patient-controlled devices for managing pain.	https://www.fiercebiotech.com/medtech/fda-designates-bd-s-wide-ranging-alaris-infusion-pump-recall-as-class-1	
33	ICT, eHealth & Domotica	Risico	114	FDA warns of cybersecurity risks in Bluetooth Low Energy-equioped medical devices	FierceBiotech	4-mrt	Bluetooth connectivity	07 Overig ICT	Cybersecurity risk Bluetooth	03 Waarschuwing/incident	he FDA has taken steps to notify healthcare providers and manufacturers about a series of cybersecurity gaps related to Bluetooth Low Energy communication that could affect certain medical devices such as wearable glucose monitors and insulin pumps as well as pacemakers, neurostimulators and hospital ultrasound machines. Dubbed SweynTooth, the collection of 12 publicly available exploits could be used to wirelessly crash a device and stop it from functioning or access central user features. The agency said it is not aware of any adverse events related to these vulnerabilities. "Medical devices are becoming increasingly connected, and connected devices have inherent risks, which make them vulnerable to security breaches," said Suzanne Schwartz, deputy director of the FDA device center's Office of Strategic Partnerships and Technology Innovation, in an agency statement. "These breaches potentially impact the safety and effectiveness of the device and, if not remedied, may lead to patient harm."	https://www.fiercebiotech.com/medtech/fda-warns-cybersecurity-risks-bluetooth-low-energy-equipped-medical-devices	
33	Medische hulpmiddelen	Ontwikkeling	115	Drug-Delivery Patch Shows Promise for an Overlooked Disease	MDDI	27-apr	oral adhesive drug-delivery patch	20 Overig	oral adhesive drug-delivery patch	01 Nieuw product	AFYX Therapeutics reported positive clinical trial results for a biodegradable oral adhesive drug-delivery patch to treat oral lichen planus (OLP), an inflammatory condition characterized by lesions and ulcers inside the mouth. Rivelin is a muco-adhesive two layered patch designed to deliver a pharmaceutical product (such as clobetasol) directly to wet tissue surfaces. It is designed to adhere to mucosal surfaces for extended periods, facilitating uni-directional delivery of a pharmaceutical agent to the target site of action impacting disease progression, while limiting delivery to surrounding areas. Image courtesy of AFYX Therapeutics A biodegradable drug-delivery patch met the primary and multiple secondary endpoints in a phase 2b study in patients with oral lichen planus (OLP), a chronic inflammatory condition characterized by lesions and ulcers inside the mouth.	https://www.mddionline.com/drug-delivery-patch-shows-promise-overlooked-disease	
33	Klinische technologie	Ontwikkeling	116	FDA Grants Breakthrough Designation for Heart Failure Device	MDDI	23-apr	VisOne	01 Actief implantaat	implantable system delivering synchronized diaphragmatic stimulation	01 Nieuw product	Portland, OR-based VisCardia is developing VisOne, an implantable system that delivers synchronized diaphragmatic stimulation (SDS) therapy for improving cardiac function. VisCardia has been granted Breakthrough Device Designation for an implantable technology to treat heart failure (HF). More specifically, the Portland, OR-based company's VisOne is a device that treats moderate to severe HF with reduced ejection fraction and preserved ventricular synchrony. The system delivers synchronized diaphragmatic stimulation (SDS) therapy. Gregg Harris, VP of Clinical and Regulatory Affairs spoke with MD+DI about VisOne and how the device has the potential to make a difference in the lives of HF patients. We implant two bi-polar leads on the underside of the diaphragm using a laparoscope. It's minimally invasive and it takes two small half-inch incisions that allow us to plant the leads onto the diaphragm. We place a small generator subcutaneously in the abdomen, which detects the cardiac activity. It then sends a small shock to the diaphragm. This just stimulates a small portion of the diaphragm. It doesn't affect breathing at all."	https://www.mddionline.com/fda-grants-breakthrough-designation-heart-failure-device	

33	In-vitro diagnostica	Ontwikkeling	117	Liquid Biopsy Test Detects More than 50 Cancer Types	MDDI	2-apr	multi-cancer early detection blood test	09 Diagnostische laboratorium testen	multi-cancer early detection blood test	02 Nieuwe therapie/techniek	Grail had a huge win in the liquid biopsy space this week. The Menlo Park, CA-based company said results of its Circulating Cell-Free Genome Atlas study show its technology can detect 50 cancer types across all stages with a very low false-positive rate. Grail has some solid results coming from its multi-cancer early detection blood test. The liquid biopsy specialist revealed data that shows its technology can detect more than 50 cancer types across all stages, with a very low false-positive rate of less than 1%, through a single blood draw. These results were published in Annals of Oncology. Grail's Circulating Cell-Free Genome Atlas (CCGA) study provided much of the data for the publication. The study included more than 15,000 participants with or without a diagnosis of cancer.	https://www.mddionline.com/liquid-biopsy-test-detects-more-50-cancer-types	
33	In-vitro diagnostica	Ontwikkeling	118	Thermo Fisher Granted CE Mark for COVID-19 Test	MDDI	26-mrt	COVID-19 Test	10 Diagnostische laboratorium testen	CE mark for COVID-19 Test	01 Nieuw product	The CE mark comes as the virus continues to rage through Europe. hermo Fisher Scientific is bringing its diagnostic detects nucleic acid from SARS-CoV-2, the virus that causes COVID-19, to Europe. The Waltham, MA-based company said earlier today it had received CE mark for the test. The test uses Applied Biosystems TaqPath Assay technology and is designed to provide patient results within four hours of a sample being received by a lab. The estimated time-to-result also includes time for sample preparation and instrument analysis.	https://www.mddionline.com/thermo-fisher-granted-ce-mark-covid-19-test	
34	Medische hulpmiddelen	Ontwikkeling	119	Mensen met CF krijgen longfunctiemeters thuis dankzij initiatief Radboudumc en NCFS	fmt gezondheidszorg	29-apr	longfuctiemeter	08 POC test/zelftest	longfunctie thuis meten	11 Overig	Mensen met taaislijmziekte (cystic fibrosis, CF) kunnen binnenkort thuis hun longfunctie meten. Dat s de uitkomst van een project dat het Radboudumc en de Nederlandse Cystic Fibrosis Stichting (NCFS) onlangs hebben gestart. Hierdoor kan op afstand de longfunctiemeting bijgehouden worden door de behandelend arts; dit biedt uitkomst in deze coronatijd.	https://fmtgezondheidszorg.nl/mensen-met-cf-krijgen-longfunctiemeters-thuis-dankzij-initiatief-radboudumc-en-ncfs/	
34	Medische hulpmiddelen	Ontwikkeling	120	Bravis ziekenhuis lost tekort aan beschermingsjassen op	fmt gezondheidszorg	29-apr	beschermjas	20 Overig	nieuw ontwikkeld beschermjas	01 Nieuw product	"Uiteindelijk hebben we een waterproefechtige stof gevonden die lijkt op Gore Tex. Dit materiaal is spatdicht en waterafstotend. De jassen zijn uitgebreid getest en goedgekeurd door onze afdeling Hygiëne Infectie Preventie.	https://fmtgezondheidszorg.nl/bravis-ziekenhuis-lost-tekort-aan-beschermingsjassen-op/	
34	Klinische technologie	Ontwikkeling	121	4 miljoen euro voor ontwikkeling nieuwe vorm van MRI-scan	fmt gezondheidszorg	11-mei	MRI-scan	11 Beeldvormende/bestraling s technieken	nieuwe contrastmiddelen te ontwikkelen voor MRI-can	02 Nieuwe therapie/techniek	LUMC-hoogleraar Radiologie Hildo Lamb (foto) coördineert het project genaamd NOVA-MRI. Het doel is om nieuwe contrastmiddelen te ontwikkelen, die in de kliniek kunnen worden gebruikt voor precisiegeneeskunde. Om dat doel te bereiken stelt het consortium 15 jonge onderzoekers aan.	https://fmtgezondheidszorg.nl/4-miljoen-euro-voor-ontwikkeling-nieuwe-vorm-van-mri-scan/	
34	In-vitro diagnostica	Risico	122	Nederlands bedrijf verkocht anderhalf miljoen onbetrouwbare coronatests	trouw	6-mei	coronatest	09 Diagnostische laboratorium testen	test onbetrouwbaar	03 Waarschuwing/incident	De test werd als Nederlands product verkocht, maar blijkt uit China te komen. De test kon ongecontroleerd de markt op omdat de Inspectiedienst alleen test controleert voor particuliere verkoop. De uitkomsten van de etst zijn zeer onbetouwbaar.	https://www.trouw.nl/binnenland/nederlands-bedrijf-verkocht-anderhalf-miljoen-onbetrouwbare-coronatests~b218dc66/	
34	ICT, eHealth & Domotica	Ontwikkeling	123	TNO ontwikkelt zoekmachine om snel kennis over covid-19 te vinden	zorgvisie	7-mei	COVID-RAPID-MINER tool	18 Artificial intelligence	dataminingtool	10 Nieuwe ontwikkeling	Kennisinstituut TNO ontwikkelde een dataminingtool op basis van artificial intelligence die snel de meest recente wetenschappelijke informatie over het coronavirus en covid-19 kan vinden en reviewen. De zogenoemde COVID-RAPID-MINER tool kan hierdoor nieuwe strategieën in kaart brengen die helpen om de covid-19-pandemie te bestrijden.	https://www.zorgvisie.nl/tno-ontwikkelt-zoekmachine-om-snel-kennis-over-covid-19-te-vinden/	
34	ICT, eHealth & Domotica	Ontwikkeling	124	Een prothese met gevoel	technisch weekblad	1-mei	armprothese met gevoel	03 Prothese/exoskeleton	armprothese met gevoel op basis van osseoïntegratie	10 Nieuwe ontwikkeling	Een kunstarm die werkt als een echte arm, doordat de zenuwen verbonden zijn met de prothese? Zes jaar geleden publiceerde Technisch Weekblad al over een veelbelovende innovatie bij Chalmers University of Technology. Sindsdien is de prothese uitgebreid getest en verder verbeterd, je kunt er nu ook mee voelen.De prothese werkt op basis van osseointegratie, waarbij de prothese met een pen aan het bot in de armstomp bevestigd zit. In de zenuwen en spieren van de stomp zijn elektroden geïmplanteerd. Die pikken signalen die uit de hersenen komen op. Via een implantaat bereiken die de prothese met een embedded besturingscomputer. Met behulp van kunstmatige intelligentie vertaalt die de signalen in een beweging. Krachtsensoren in de duim van de prothese meten op hun beurt de druk die oo de duim uitgeoefend wordt en sturen die signalen naar het ingebouwde computertje. Daar worden ze omgezet in elektrische prikkels die worden doorgegeven aan de zenuwen in de stomp en zo het brein bereiken. Dit geeft de drager als het ware gevoel in zijn hand, waardoor hij deze veel preciezer kan gebruiken.	https://www.technischweekblad.nl/nieuws/een-prothese-met-gevoel	
34	Klinische technologie	Ontwikkeling	125	Een magnetisch zaadje voor het lokaliseren van tumoren	ict health	18-jun	magnetisch zaadje	11 Beeldvormende/bestraling s technieken	zaadje localiseert tumor	10 Nieuwe ontwikkeling	In de loop van dit jaar, naar verwachting net na de zomer, zal de Sirius Pintuition beschikbaar komen. Dit is een innovatief systeem dat gebruik maakt van een nieuwe methode waarmee tumoren in de borst tijdens operaties makkelijker te lokaliseren zullen zijn. Onlangs ontving de ontwikkelaar van het systeem, de medtech-startup Sirius Medical, het benodigde CE-keurmerk voor de Sirius Pintuition.	https://www.ictheallh.nl/nieuws/een-magnetisch-zaadje-voor-het-lokaliseren-van-tumoren/	
34	ICT, eHealth & Domotica	Ontwikkeling	126	Eerste stap naar contactloos braille	technisch weekblad	18-jun	contactloos braille	20 Overig	contactloos braille	10 Nieuwe ontwikkeling	Onderzoekers van de Duitse universiteit van Bayreuth presenteren een model, waarmee blinden contactloos braille kunnen lezen: de HaptiRead. Volgens de onderzoekers kan het systeem nuttig zijn in de publieke ruimte waar spraak te privacygevoelig is en hygiëne belangrijk, bijvoorbeeld bij pinautomaten en ziekenhuizen.	https://www.technischweekblad.nl/nieuws/eerste-stap-naar-contactloos-braille	
34	Klinische technologie	Ontwikkeling	127	Radboudumc introduceert nieuwe behandeling met laser voor glioblastoom	medical facts	25-jun	laser	11 Beeldvormende/bestraling s technieken	laser ter bestrijding moeilijk opereerbare tumoren in hersenene	02 Nieuwe therapie/techniek	In het najaar introduceert het Radboud een neiwue behandeling waarbij de tumor van binnenuit verhit wordt met energierijk licht.	https://www.medicalfacts.nl/2020/06/25/radboudumc-introduceert-nieuwe-behandeling-met-laser-voor-glioblastoom/	

34	In-vitro diagnostica	Risico	128	Serologische sneltesten onbetrouwbaar, maar 'de markt is vrij'	medisch contact	14-mei	sneltest covid	08 POC test/zelftest	de betrouwbaarheid van de zogeheten POCT-testen (point-of-care testen) enorm varieert.	03 Waarschuwing/incident	Sneltesten naar de aanwezigheid van antilichamen tegen SARS-CoV-2 voldoen niet aan de eisen voor individuele patiëntendiagnostiek. Dat blijkt uit een validatieonderzoek door de Taskforce Serologie van de Landelijke Coördinatie Testcapaciteit, dat is gepubliceerd door het RIVM. De Taskforce raadt het gebruik van de sneltesten af, omdat ze niet betrouwbaar zijn en er een te grote hoeveelheid foutpositieve en foutnegatieve uitslagen zijn.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/serologische-sneltesten-onbetrouwbaar-maar-de-markt-is-vrij-.htm	
34	ICT, eHealth & Domotica	Risico	129	Medicatiefouten door gebruiksonvriendelijke systemen	icthealth	2-jul	computersysteem	05 EPD/ patiëntgegevens	gebruiksonvriendelijk vergroot kans op fouten	03 Waarschuwing/incident	it een verkennend onderzoek van het Rijksinstituut voor Volksgezondheid en Milieu (RIVM) blijkt dat gebruiksonvriendelijke computersystemen voor het bijhouden van patiëntinformatie tot fouten bij het voorschrijven van medicijnen kunnen leiden.	https://www.icthealth.nl/nieuws/medicatiefouten-door-gebruiksonvriendelijke-systemen/	
34	ICT, eHealth & Domotica	Risico	130	RIVM-website Infectieradar tijdelijk offline na datalek	skipr	6-jun	datalek	05 EPD/ patiëntgegevens	datalek	03 Waarschuwing/incident	ij de website Infectieradar, waarmee het RIVM informatie verzamelt over gezondheidsklachten die kunnen wijzen op corona, is sprake geweest van een datalek. Daardoor waren persoonlijke gegevens in te zien, zo bevestigt een woordvoerder na berichtgeving van de NOS.	https://www.skipr.nl/nieuws/rivm-website-infectieradar-tijdelijk-offline-na-datalek/	
34	ICT, eHealth & Domotica	Ontwikkeling	131	Philips biosensor monitort COVID-19 patiënten op afstand	icthealth	29-mei	De BX100,	06 Wearables, incl sensoren op huid	een nieuwe draadloze en draagbare biosensor	01 Nieuw product	De BX100, een nieuwe draadloze en draagbare biosensor, ook wel een slimme pleister genoemd, van Philips heeft onlangs de FDA goedkeuring en een CE-markering ontvangen. Daarmee mag de biosensor ingezet worden als hulpmiddel bij het monitoren van COVID-19 patiënten in ziekenhuizen. Daarmee kunnen zorgverleners op afstand op de hoogte blijven en gewaarschuwd worden wanneer de gezondheidstoestand van een patiënt (plotseling) verslechterd	https://www.icthealth.nl/nieuws/philips-biosensor-monitort-covid-19-patienten-op-afstand/	
34	ICT, eHealth & Domotica	Ontwikkeling	132	Eerste versie van corona-app gepubliceerd	skipr	27-mei	corona app	04 App	Eerste versie van corona-app	11 Overig	Een eerste versie van de corona-app die de overheid wil laten maken, is klaar. De makers van de app hebben de code woensdag op de ontwikkelaarsplatforms Github en Figma gezet. Ze vragen de buitenwereld om reacties en suggesties en benadrukken dat de app nog niet klaar is.Minister Hugo de Jonge (Volksgezondheid) hoopt dat de app in juni gelest kan worden. Volgende maand moet dan ook duidelijk worden wanneer de app beschikbaar komt voor het publiek, zei de bewindsman na crisisberaad over het coronavirus. (ANP)	https://www.skipr.nl/nieuws/eerste-versie-van-corona-app-gepubliceerd/	
34	Medische hulpmiddelen	Risico	133	Nederland koopt miljoenen ondeugdelijke mondkapjes	skipr	27-mei	mondkapjes	20 Overig	ondeugdelijke mondkapjes	03 Waarschuwing/incident	Eén op de tien mondkapjes die het Landelijk Consortium Hulpmiddelen (LCH) heeft aangeschaft, is afgekeurd. Deze mondkapjes voldoen niet aan de kwaliteitseisen en worden niet verspreid onder zorginstellingen. Tot nu toe heeft het LCH namens het ministerie van Volksgezondheid 47,2 miljoen medische mondkapjes naar Nederland gehaald. Een woordvoerder van VWS bevestigde berichtgeving daarover van het AD.	https://www.skipr.nl/nieuws/nederland-koopt-miljoenen-ondeugdelijke-mondkapjes/	
34	Medische hulpmiddelen	Ontwikkeling	134	Videocamera alarmeert automatisch bij epileptische aanvallen	icthealth	8-mei	videocamera's	20 Overig	epilepsie-alarmsysteem	20 Overig	derzoekers van het Leids Universitair Medisch Centrum (LUMC) en het expertisecentrum voor epilepsie en slaapgeneeskunde SEIN hebben een epilepsie-alarmsysteem ontwikkeld: een videocamera die automatisch alarm slaat op het moment dat iemand een epileptische aanval hee	https://www.icthealth.nl/nieuws/videocamera-alarmeert-automatisch-bij-epileptische-aanvallen/	
34	Medische hulpmiddelen	Ontwikkeling	135	Wearable zweetsensor om sepsis te herkennen in de maak	icthealth	4-mei	zweetsensor	06 Wearables, incl sensoren op huid	zweetsensor om sepsis te herkennen	01 Nieuw product	en team van onderzoekers, onder leiding van de TU Eindhoven, werkt aan de ontwikkeling van een wearable zweetsensor. Die moet, in combinatie met data-analyse, de semi-continue sepsis-monitoring van patiënten in het ziekenhuis mogelijk maken. Op die manier kan de sepsis tijdig herkend worden en het aantal complicaties dat ermee gepaard gaat aanzienlijk verminderd worden.	https://www.icthealth.nl/nieuws/wearable-zweetsensor-om-sepsis-te-herkennen-in-de-maak/	
34	Implantaten	Ontwikkeling	136	DePuy Launches New Interbody Implant For Degenerative Disc Disease	MDDI	7-mei	CONCORDE LIFT Expandable Interbody device	02 Niet actief implantaat	Nieuw implantaat als vervaning tussenwervelschijf	02 Nieuwe therapie/techniek	DePuy Synthes, an orthopedic and neurosurgery company owned by Johnson & Johnson, recently announced the launch of their new flagship technology, the CONCORDE LIFT Interbody Implant. The new implantable device was designed to help treat patients suffering from degenerative disc disease, a condition that can cause extreme pain from a damaged disc in the spine. The implantable device was designed as part of a new procedural solution that can simplify minimally invasive spine surgery procedures used to help restore disc height in the spinal column. This is typically done through the process of spinal fusion, a surgical procedure that places bone or bone-like material within the space between two spinal vertebrae. In an effort to simplify the procedure, DePuy created the CONCORDE LIFT implant to provide patients with a device that can specifically fit each patient's anatomy due to a continuous expansion mechanism.	https://www.mddionline.com/orthopedic/depuy-launches-new-interbody-implant-degenerative-disc-disease	
34	Implantaten	Ontwikkeling	137	Edwards Makes Gains in Tricuspid Regurgitation Repair with CE Mark	MDDI	18-mei	Pascal repair system	02 Niet actief implantaat	Tricuspid Regurgitation Repair	01 Nieuw product	The Irvine, CA-based company said its Pascal System has not yet been approved in the U.S. The Irvine, CA-based company said the Pascal repair system demonstrated high procedural success and significant clinical improvements in patients with challenging tricuspid anatomy and severe TR. Sustained TR reduction was observed at 30 days, with 85% of patients seeing a reduction to TR ≤2+ on a five-grade scale. "Edwards is the first company to introduce multiple transfemoral tricuspid repair therapies in Europe, providing physicians with both leaflet repair and annular reduction therapies to help meet their patients' needs."	https://www.mddionline.com/business/edwards-makes-gains-tricuspid-regurgitation-repair-ce-mark	https://cardiovascularnews.com/ce-mark-pascal-clip-based-system-for-transcatheter-tricuspid-repair/

34	Implantaten	Risico	138	Medtronic Issues Recall for HVAD Pump Outflow Graft	MDDI	29-mei	HVAD pump outflow graft and outflow graft strain relief	01 Actief implantaat	Recall HVAD pump outflow graft and outflow graft strain relief	04 Recall	The Dublin-based company is recalling the HeartWare HVAD pump outflow graft and outflow graft strain relief because of the risk of breaks and tears during the pre-implant pump assembly process. FDA has identified this as a Class I recall. Medtronic is recalling its HeartWare HVAD pump outflow graft and outflow graft strain relief because of the risk of breaks and tears during the pre-implant pump assembly process. FDA has identified this as a Class I recall. The Dublin-based company said it has received 92 complaints. The recalled products according to FDA's release are: HeartWare HVAD Pump Outflow Graft and Outflow Graft Strain Relief *HVAD Pump Outflow Graft: 1125* *HVAD Pump Implant Kit: 1103* *HVAD Implant Accessories Kit: 1153* Distribution Dates: March 1, 2018 to April 1, 2020 Medtronic said the use of the affected products may cause serious patient harm including dizziness, loss of consciousness, bleeding, fluid buildup around the heart, additional medical procedures, and death.	https://www.mddionline.com/cardiovascular/medtronic-issues-recall-hvad-pump-outflow-graft	https://www.ictmd.com/news/medtronic-recalls-parts-its-heartware-vad-system
34	ICT, eHealth & Domotica	Risico	139	New App Predicts Blood Glucose Levels 60 Minutes into the Future	MDDI	9-jun	Diabits app	04 App	App die bloedsuikerwaarden over 60 minuten voorspelt.	01 Nieuw product	Bio Conscious Technologies says its AI-powered Diabits app is capable of predicting blood glucose levels an hour into the future, an improvement on industry-leading continuous glucose monitoring systems that offer 20-minute predictions. There's a new, AI-powered diabetes app that claims to accurately predict blood glucose levels sooner than the industry-leading continuous glucose monitoring (CGM) systems, which currently tout 20-minute glucose value prediction capabilities. Bio Conscious Technologies said an in-house silico study of its Diabits AI algorithm demonstratec its ability to provide 60-minute blood glucose value predictions. The Vancouver, British Columbia-based company says the app is designed for people with diabetes who use a CGM to monitor their daily blood sugar fluctuations	https://www.mddionline.com/diabetes/new-app-predicts-blood-glucose-levels-60-minutes-future	
34	Klinische technologie	Ontwikkeling	140	It's Finally Here ... FDA Clears Abbott's Freestyle Libre 2 iCGM	MDDI	15-jun	Freestyle Libre 2	08 POC test/zelftest	Nieuwe versie freestyle libre non-invasieve continue glucose monitor patch.	01 Nieuw product	Abbott's Freestyle Libre 2 iCGM can be used in adults and children over age 4 for a 14-day period. The first generation of the Freestyle Libre won FDA approval in 2017. The device was called a game-changer for continuous glucose monitoring because it could be used as a replacement for blood glucose monitoring (BGM) for adults. The second generation of the device differs because, in addition to having a pediatric indication, it has Bluetooth capabilities and optional alarms. "It's a real leapfrog in CGM technology," Taub said. "It has best-in-class accuracy with 14-day performance. It measures glucose every minute. It also introduces optional alarms to the Freestyle Libre platform of products which is great. Now patients with diabetes can understand when their high glucose threshold or low glucose threshold autonatically. The system alarms and tells them to scan to see what their glucose level is. With each reading, they see what their glucose value is and what direction it's heading..."	https://www.mddionline.com/diabetes/its-finally-here-%E2%80%A6-fda-clears-abbotts-freestyle-libre-2-icgm	
34	Implantaten	Ontwikkeling	141	Medtronic Moves the Needle in TAVI with New Indication	MDDI	23-jun	Evolut Transcatheter Aortic Valve Implantation system	02 Niet actief implantaat	Uitbreiding indicaties voor TAVI	12 Markttoelating	The Dublin-based company said it has received CE mark for an expanded indication of its Evolut Transcatheter Aortic Valve Implantation system to treat patients with severe native aortic stenosis who are at a low risk of surgical mortality. The Dublin-based company said the new indication is for patients with severe native aortic stenosis who are at a low risk of surgical mortality. The Evolut TAVI platform also received a new indication approval that allows for the treatment of patients with bicuspid aortic valves who are at intermediate, high and extreme risk of surgical mortality.	https://www.mddionline.com/cardiovascular/medtronic-moves-needle-tavi-new-indication	
34	Implantaten	Ontwikkeling	142	New Titanium Foam Spinal Implant Comes Pre-Attached to Disposable Delivery Device	MDDI	30-jun	CancelleX lumbar interbodies	02 Niet actief implantaat	CancelleX lumbar interbodies	01 Nieuw product	Image courtesy of Xenco Medical New Titanium Foam Spinal Implant Comes Pre-Attached to Disposable Delivery Device Xenco's CancelleX porous titanium implant is optimized for energy absorption and bone in-growth, and designed to achieve bone-like mechanical properties. Surgical implant maker Xenco Medical continues to flex is innovation muscles, most recently with the launch of an injection-molded titanium foam implant that comes pre-attached to a disposable delivery device. "Optimized for energy absorption and bone in-growth, the interconnected network of pores that permeate each CancelleX porous titanium implant serve to achieve bone-like mechanical properties," said Xenco Medical Founder and CEO Jason Haider (pictured above).	https://www.mddionline.com/orthopedic/new-titanium-foam-spinal-implant-comes-pre-attached-disposable-delivery-device	
34	Implantaten	Ontwikkeling	143	Medtronic's Micra AV TPS receives CE mark	Cardiac Rhythm News	17-jun	Micra AV	01 Actief implantaat	Nieuwe draadloze pacemaker van Medtronic	12 Markttoelating	Medtronic has received CE mark for Micra AV Transcatheter Pacing System (TPS), the world's smallest pacemaker with atrioventricular (AV) synchrony. Micra AV is indicated for the treatment of patients with AV block, a conditon in which the electrical signals between the chambers of the heart (the atria and the ventricle) are impaired. Medtronic now offers the first and only CE Mark approved leadless pacemaker portfolio, expanding the number of potential candidates for this groundbreaking technology throughout the world. Identical in size and shape to the original Micra TPS, Micra AV has several additional internal atrial sensing algorithms which detect cardiac movement, allowing the device to adjust pacing in the ventricle to coordinate with the atrium, providing "AV synchronous" pacing therapy to patients with AV block.	https://cardiacrhythmnews.com/medtronics-micra-av-tps-receives-ce-mark/	https://www.medgadget.com/2020/06/medtronic-micra-av-transcatheter-heart-pacer-cleared-in-eu.html

34	Systeem	Ontwikkeling	144	Eudamed update: Phased implementation planned for European medical device, IVD database	Emergo	12-mei	Eudamed	16 Wet en regelgeving	Vertraging Eudamed	05 Standaardisatie, wet-/regelgeving/NoBo	The implementation of the European Database for Medical Devices, Eudamed, has been delayed by two years and the implementation of the Medical Devices Regulation (MDR) has been delayed by one year. The European Commission has informed Emergo that parts of Eudamed will be made available to users before the official Eudamed date of application in May 2022.	https://www.emergobyul.com/blog/2020/05/eudamed-update-phased-implementation-planned-european-medical-device-ivd-database	
34	Systeem	Ontwikkeling	145	TÜV SÜD becomes fourth Notified Body designated to European IVDR	Emergo	19-jun	Notified body	20 Overig	Notified body IVDs	05 Standaardisatie, wet-/regelgeving/NoBo	German Notified Body TÜV SÜD has obtained designation to issue CE Mark certificates under the European In-vitro Diagnostic Medical Devices Regulation (IVDR). There are now four Notified Bodies designated to the IVDR ahead of the Regulation's May 2022 date of application, according to the NANDO database.	https://www.emergobyul.com/blog/2020/06/tuv-sud-becomes-fourth-notified-body-designated-european-ivdr	
34	Klinische technologie	Risico	146	VIVA's Paclitaxel Analysis Finds Increased Mortality Risk, But No Dose Association; Lead Author Encourages Close Read	Endovascular Today	27-mei	paclitaxel gecoate ballonnen en paclitaxel agfevende stents	20 Overig	veiligheid	11 Overig	Earlier this month, VIVA Physicians announced the publication of an analysis of mortality and paclitaxel-coated devices by Krishna Rocha-Singh, MD, et al, which is available online ahead of print in Circulation. The data were also presented by Gary Ansel, MD, during a Charing Cross virtual session on May 25. The investigators performed an individual patient-level data (IPD) analysis of the safety of paclitaxel-containing devices (PTXD), further exploring the increased mortality signal first identified by Konstantinos Katsanos, MD, et al in their December 2018 Journal of the American Heart Association publication. The VIVA analysis, which included 2,165 patients across eight studies with a median follow-up of 4 years, also identified an increased mortality risk associated with PTXD use. However, it found a weaker mortality signal, and no drug-dose relationship was established, in contradistinction to the findings of Katsanos et al's study-level analysis.	https://evtoday.com/news/viva's-paclitaxel-analysis-finds-increased-mortality-risk-but-no-dose-association-lead-author-encourages-close-read	https://www.tctmd.com/news/recovered-paclitaxel-pad-data-shift-mortality-picture
34	Implantaten	Risico	147	Allergan receives FDA warning over recalled breast implant safety studies	FierceBiotech	15-mei	Natrelle gel-filled breast implants	02 Niet actief implantaat	FDA warning letter	03 Waarschuwing/incident	The FDA issued two warning letters to breast implant manufacturers this week, including Allergan for failing to complete postmarket safety studies documenting the risks of two implant models the company took off the worldwide market last year.	https://www.fiercebiotech.com/medtech/allergan-receives-fda-warning-over-recalled-breast-implant-safety-studies	
34	Implantaten	Risico	148	FDA Updates Information on Allergan's Actions to Reach Patients about BIOCELL Breast Implant Recall	FDA	1-jun	Natrelle BIOCELL textured breast implants and tissue expanders	02 Niet actief implantaat	BIA-ALCL	11 Overig	Based on the currently available information, including the newly submitted data, FDA's analysis demonstrates that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences and potentially death from BIA-ALCL.	https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue	
34	Implantaten	Risico	149	Case Series Hints at Excess Stent Thrombosis During COVID-19	Medscape	9-jun	cardiovascular stents and COVID 19	02 Niet actief implantaat	stent thrombose	11 Overig	A group of interventional cardiologists from Spain have published details on a series of four cases of stent thrombosis (ST) in patients with COVID-19 seen at their hospital. The authors suggest that these cases are related to virus-related hypercoagulability triggering thrombotic complications.	https://www.medscape.com/viewarticle/932021?nlid=135910_3923&src=WNL_mdplsnews_200612_mscpedit_card&uac=61059SR&spon=2&impID=2417241&faf=1	
34	ICT, eHealth & Domotica	Ontwikkeling	150	A Wearable That Has the Potential to Detect COVID-19	MDDI	19-jun	Aura	06 Wearables, incl sensoren op huid	ontwikkeling weerable voor COVID-19	10 Nieuwe ontwikkeling	Empatica and BARDA's Division of Research, Innovation, and Ventures (DRIVe) began to develop a digital biomarker that predicts respiratory infections. Preliminary findings have been promising, showing a strong correlation between viral shedding and changes in a person's physiology. Now Empatica will be sponsored to run a validation trial specific to early detection of COVID-19.	https://www.mddionline.com/covid-19/wearable-has-potential-detect-covid-19?ADTRK=InformaMarkets&elq_mid=13544&elq_cid=4451694	
34	Klinische technologie	Risico	151	MHRA: Warning to be added to paclitaxel device IFUs in Europe	Vascular News	16-jun	paclitaxel gecoate ballonnen en paclitaxel agfevende stents	20 Overig	Field safety notice - Update IFU	11 Overig	In a new field safety notice, the UK Medicines and Healthcare products Regulatory Agency (MHRA) states that a warning and clinical summary section will be added to the instructions for use (IFU) of 12 paclitaxel-coated balloons and paclitaxel-eluting stents used in the treatment of peripheral arterial disease (PAD) of the lower limbs.	https://vascularnews.com/warning-to-be-added-to-paclitaxel-coated-device-ifus-in-europe/	
34	In-vitro diagnostica	Ontwikkeling	152	Dana-Farber researchers detect early kidney cancer with DNA methylation-screening blood test	FierceBiotech	22-jun	Mogelijke test voor vroege detectie nierkanker	09 Diagnostische laboratorium testen	Mogelijke test voor vroege detectie nierkanker	02 Nieuwe therapie/techniek	Using a DNA-sequencing blood test, researchers at Dana-Farber Cancer Institute found they were able to spot some of the earliest signs of kidney cancer, a potentially fatal disease that currently lacks a broad screening exam. In early studies, the test was nearly 100% accurate at identifying people with kidney cancer based on their blood samples, using a combination of high-throughput sequencing and analyses of DNA methylation—the chemical process that tags certain sequences of genetic code with additional molecules that alter their function. It's a different method than other DNA-based liquid biopsy tests, which may read through the code itself to search for specific mutations linked to different cancers. Instead, the test hunts for DNA released by cancer cells into the bloodstream marked with abnormal methylation patterns compared to DNA from healthy cells, which can be used as clearer evidence of the disease.	https://www.fiercebiotech.com/medtech/dana-farber-researchers-detect-early-kidney-cancer-methylation-screening-blood-test	
34	ICT, eHealth & Domotica	Ontwikkeling	153	FDA clears its first prescription video game treatment for ADHD	FierceBiotech	15-jun	EndeavorRx	07 Overig ICT	Spel als onderdeel behandeling ADHD	12 Markttoelating	The FDA has cleared its first video game for children with attention deficit hyperactivity disorder (ADHD), allowing Akili Interactive's EndeavorRx to be prescribed as a digital therapeutic. Played on a touchscreen, the software provides challenges and stimuli that target the brain's neural systems linked to focus, cognitive function and multitasking. It is designed to be used as part of a wider therapy regimen, which may also include medication or educational programs, to help improve attention in children 8 to 12 years old.	https://www.fiercebiotech.com/medtech/fda-clears-its-first-prescription-video-game-treatment-for-adhd	

34	Klinische technologie	Ontwikkeling	154	Superseturated Oxygen Therapy Cleared in EU to Treat Widowmaker Heart Attacks	medgadget	6-mei	Supergesatureerde zuurstof toediener	20 Overig	CE-markering	12 Markttoelating	ZOLL Medical, a part of the Asahi Kasei Group, won EU clearance for its SuperSaturated Oxygen (SSO2) Therapy System to be used to minimize the damage that heart attacks cause within heart muscle. SSO2 is the only option beyond percutaneous coronary intervention (stenting) that can help stricken patients recover with improved outcomes. These days, heart attacks are usually treated by placing stents at the sites of narrowing coronary arteries. This has become a standard of care and interventional cardiologists can accurately place stents within minutes. Although blood flow is restored, affected parts of the heart continue to be starved of oxygen. SuperSaturated Oxygen allows interventional cardiologists to push hyperbaric levels of oxygen straight to oxygen-deprived myocardium right after placing a stent. This helps damaged tissue to recover, leading to reduced	https://www.medgadget.com/2020/05/supersaturated-oxygen-therapy-cleared-in-eu-to-treat-widowmaker-heart-attacks.html	9
34	ICT, eHealth & Domotica	Ontwikkeling	155	LifeSignals Receives CE Mark for ECG Remote Monitoring Patch	medgadget	8-mei	ECG wearable	06 Wearables, incl sensoren op huid	CE-markering	12 Markttoelating	LifeSignals, based in Fremont, California, announced that it received the CE Mark for its LifeSignals ECG Remote Monitoring Patch. The patch, integrated with a remote monitoring platform, is designed as a continuous electrocardiography (ECG) and heart rate monitor. The ECG Remote Monitoring Patch is disposable and captures data for up to three days. The device is lightweight and splash-proof. Each patch features the company's patented LC1100 Life Signal Processor, which operates on a coin-cell battery and detects, stores, and securely transmits patient data to a cloud-based platform that is accessible by healthcare professionals	https://www.medgadget.com/2020/05/lifesignals-receives-ce-mark-for-ecg-remote-monitoring-patch.html	
34	ICT, eHealth & Domotica	Ontwikkeling	156	VitalPatch Wins FDA Emergency Use Authorization for Cardiac Monitoring in COVID Patients	medgadget	8-mei	ECG wearable	06 Wearables, incl sensoren op huid	FDA emergency use toelating	12 Markttoelating	VitalConnect announced that it has received FDA Emergency Use Authorization status for use of its VitalPatch to detect changes in the QT interval of hospitalized patients undergoing drug treatment for COVID-19. Hydroxychloroquine and chloroquine, used to treat some COVID-19 patients, are associated with risk of prolonged QT interval that can lead to life-threatening arrhythmias. VitalPatch allows clinicians to remotely and continuously monitor patients at risk of QT prolongation due to COVID-19 treatment.	https://www.medgadget.com/2020/05/vitalpatch-wins-fda-emergency-use-authorization-for-cardiac-monitoring-in-covid-patients.html	
34	Klinische technologie	Ontwikkeling	157	AirTouch Portable X-Ray Receives FDA Clearance, Can Be Used for COVID Diagnosis	medgadget	11-mei	Draagbare x-ray	11 Beeldvormende/bestraling s technieken	FDA toelating	12 Markttoelating	Aspenstate announced that it has received FDA clearance for the AirTouch, a lightweight portable X-ray system that could be particularly useful for quickly obtaining chest X-rays of COVID-19 patients. The handheld device weighs in at 5.5 pounds (2.5 Kg) and resembles a large digital camera with a touchscreen. AirTouch acquires images with the push of a button and can wirelessly transmit them to PACS (clinical image storage system), without the need for a computer. Its battery charges within two hours and can capture up to 300 exposures per charge. Its portability has already made it useful in drive-through screening centers in South Korea, according to the company	https://www.medgadget.com/2020/05/airtouch-portable-x-ray-receives-fda-clearance.html	
34	Klinische technologie	Ontwikkeling	158	aScope 4 Cysto Disposable Cystoscope Released by Ambu	medgadget	13-mei	Disposable cystoscoop	13 Scopen & camera's	Nieuw product	01 Nieuw product	Ambu, a Danish company, is releasing a single-use flexible cystoscope. Used for visualization within the bladder during diagnostic and interventional procedures, the Ambu aScope 4 Cysto comes ready to go in its sterile packaging and is disposed of once a procedure is complete. There is no reprocessing involved, the device doesn't need to be repaired, and a clinical practice simply needs to keep stock of the scopes to provide relevant services. The chance of transferring an infection between patients drops to essentially zero.	https://www.medgadget.com/2020/05/ascope-4-cysto-disposable-cystoscope-released-by-ambu.html	
34	ICT, eHealth & Domotica	Ontwikkeling	159	Butterfly TeleGuidance for Remote Ultrasound Exams During COVID Pandemic	medgadget	18-mei	Echo op afstand	11 Beeldvormende/bestraling s technieken	Software om op afstand echobeelden te laten maken en bekijken	01 Nieuw product	Butterfly Network, a maker of portable ultrasound wands that can turn a smartphone into a complete ultrasound system, has unveiled its Butterfly TeleGuidance that lets just about anyone do a scan. The system relies on a physician, or another certified clinician, to guide the user remotely using Butterfly's software. It links the Butterfly ultrasound and the smartphone it's connected to with a clinician's computer, who may be very far away. The clinician can position, move, and rotate augmented reality signs that describe how to manipulate the ultrasound wand while talking to the individual performing the exam and seeing what they are seeing.	https://www.medgadget.com/2020/05/butterfly-teleguidance-for-remote-ultrasound-exams-during-covid-pandemic.html	
34	In-vitro diagnostica	Ontwikkeling	160	Paper Device Rapidly Measures Lithium Levels in Blood	medgadget	22-mei	Snel test Lithium gehalte	08 POC test/zelftest	Li bloedtest	02 Nieuwe therapie/techniek	Researchers at Hokkaido University in Japan have developed a paper-based point-of-care device which can measure lithium levels in a drop of blood. The device could help patients with bipolar disorder to keep track of their blood lithium levels. Lithium carbonate is used to treat bipolar disorder, but must be administered carefully as the concentration range in which the drug is therapeutically active is close to its toxic range. This means that patients require regular blood tests to make sure that they are not receiving too high a dose of the drug. At present, these blood tests need large blood samples and expensive equipment to run, and not all testing labs can perform them. To address this, the Japanese researchers have developed an inexpensive paper-based device to detect lithium in the blood, which could be used in a doctor's office, or even at home by a patient.	https://www.medgadget.com/2020/05/paper-device-rapidly-measures-lithium-levels-in-blood.html	

34	In-vitro diagnostica	Ontwikkeling	161	Automated Robot Takes Swabs for Safe Covid-19 Testing	medgadget	2-jun	Robot om swab tbv COVID diagnostiek af te nemen	10 Robotica	Aankodiging nieuw product	01 Nieuw product	Testing people for COVID-19 typically involves performing a throat swab to collect a sample for processing. Clinicians performing this task have to wear a complete package of personal protective equipment (PPE), something that can be very uncomfortable over long periods of time. Moreover, since sampling is now widely performed outside of a clinical facility and the weather is hitting summer temperatures in the northern hemisphere, the discomfort for clinical staff can be harrowing. Now, a team of robotics engineers at the University of Southern Denmark have developed a device that can automatically perform throat swabs without a human clinician being in the vicinity. The robot reaches into the throat and moves a swab against the selected tissue within. Once the sample is collected, it deposits the swab into a glass jar and screws its top closed.	https://www.medgadget.com/2020/06/automated-robot-takes-swabs-for-safe-covid-19-testing.html	
34	ICT, eHealth & Domotica	Ontwikkeling	162	Ocutrx 8K 3D Eye Surgery Imaging System Unveiled	medgadget	9-jun	AR bril oogchirurgie	17 Augmented/virtual reality	Aankodiging nieuw product	01 Nieuw product	Ocutrx, an augmented reality (AR) start-up based in Irvine, California, is releasing an ophthalmology visualization system designed to make it easier for surgeons to perform procedures. Right now, ophthalmologists have to remain in constrained positions for long periods of time as they work with a microscope, but the OR-Bot from Ocutrx helps to alleviate some of the limitations of eye surgery by allowing the camera to be separate from the standard optical microscope, thereby giving a great deal of freedom in terms of how the surgical field can be visualized and worked on.	https://www.medgadget.com/2020/06/ocutrx-8k-3d-eye-surgery-imaging-system-unveiled.html	
34	In-vitro diagnostica	Ontwikkeling	163	Breathalyzer to Detect COVID-19 in Seconds	medgadget	10-jun	Adem sneltest COVID-19	08 POC test/zelftest	Techniek voor COVID-19 sneltest	02 Nieuwe therapie/techniek	Being able to tell, in a matter of seconds, whether someone is infected with the virus that causes COVID-19 would certainly help put a halt to the ongoing pandemic. Existing tests typically involve a deep nasal swab to obtain enough fluid sample, which has to be transferred to a laboratory machine for processing, with the results usually available many hours or even days after. There are five minute tests on the market, but those still require an expensive machine at each testing site. Now, researchers at Ohio State University have developed and are testing a breathalyzer that can detect metabolites related to a COVID-19 infection within fifteen seconds. The technology may allow for mass screenings of travelers at airports and those attending large public events, as well as any facility that wants to help prevent infections.	https://www.medgadget.com/2020/06/breathalyzer-to-detect-covid-19-in-seconds.html	
34	Klinische technologie	Ontwikkeling	164	Medtronic's MiniMed 780G with Artificial Pancreas Capabilities Cleared in EU	medgadget	18-jun	Kunstmatige pancreas	20 Overig	CE-markering	12 Markttoelating	Medtronic won the EU CE Mark for its MiniMed 780G closed loop insulin pump that features both Medtronic's own SmartGuard algorithm and MD-Logic, an algorithm developed by DreaMed Diabetes, a small Israeli firm. The system, indicated to be used by patients with type 1 diabetes between ages 7 and 80, automatically delivers both basal insulin and correcting boluses every five minutes, if necessary.	https://www.medgadget.com/2020/06/medtronics-minimed-780g-with-artificial-pancreas-capabilities-cleared-in-eu.html	
35	Klinische technologie	Ontwikkeling	165	Primeur in ziekenhuis Noordwest Alkmaar; slimme bril helpt bij hart- en vaatoperaties	fmt gezondheidszorg	7-jul	'chirurgische slimme bril'	06 Wearables, incl sensoren op huid	'chirurgische slimme bril'	10 Nieuwe ontwikkeling	De bril is uitgerust met een microfoon en twee camera's, waaronder een met een optische zoomlens. De expert op afstand kan deze camera bedienen en desgewenst in close up de voortgang van de operatie volgen. De arts kan de bril bedienen met spraakcommando's. Het is wereldwijd voor het eerst dat deze innovatie wordt toegepast. Noordwest werkt ervoor samen met Medtronic, één van 's werelds grootste bedrijven op het gebied van medische technologie. Tijdens de ingreep kon een technisch expert van Medtronic de arts ondersteunen tijdens het plaatsen van een vaatprothese via de liezen.	https://fmtgezondheidszorg.nl/primeur-in-ziekenhuis-noordwest-alkmaar-slimme-bril-helpt-bij-hart-en-vaatoperaties/	
35	Klinische technologie	Ontwikkeling	166	Eerste Nederlandse hartpatiënten krijgen nieuw type draadloze minipacemaker	fmt gezondheidszorg	22-jul	micra AV	19 Overig	nieuwste type minipacemaker	11 Overig	De Micra-pacemaker is een draadloze minipacemaker die voor het eerst in 2015 werd geïmplanteerd in Nederland. Waar een klassieke pacemaker onder de huid in de bovenborst wordt geïmplanteerd en met twee vastgemaakte draadjes (leads) wordt verbonden met het hart, wordt de Micra-pacemaker rechtstreeks in het hart geïmplanteerd. In drie grote ziekenhuizen in Nederland kregen onlangs de eerste Nederlandse hartpatiënten het nieuwste type draadloze minipacemaker. In het St. Antonius Ziekenhuis in Nieuwegein werd tijdens de implantatie van de kleine pacemaker gebruikgemaakt van een slimme bril. Via deze bril stond Prof. dr. Lucas Boersma, in contact met een productexpert van Medtronic.	https://fmtgezondheidszorg.nl/eerste-nederlandse-hartpatienten-krijgen-nieuw-type-draadloze-minipacemaker/	
35	Medische hulpmiddelen	Ontwikkeling	167	Pijnstillende 'bij' zorgt voor verlichting bij dialysepatiënten	medicalfacts	4-aug	pijnstillende 'bij'	20 Overig	plaatselijke verdoving middels trilling en kou	11 Overig	Het apparaat in de vorm van een bij zorgt door een combinatie van trilling en kou voor pijnstilling bij het prikken. Door een minuutleng op de prikplek het appreatje te houden, treedt er plaatselijke verdoving op.	https://www.medicalfacts.nl/2020/08/04/pijnstillende-bij-zorgt-voor-verlichting-bij-dialysepatienten/	
35	ICT, eHealth & Domotica	Ontwikkeling	168	Algoritme kan screening borstkanker verbeteren	medisch contact	9-jul	algoritme	18 Artificial intelligence	algoritme bij screening borstkanker	02 Nieuwe therapie/techniek	Een nieuw algoritme om het risico op borstkanker te voorspellen, kan bevolkingsonderzoek op den duur effectiever en efficiënter maken. Dat betogen Inge Lakeman e.a. (o.a. LUMC, Erasmus MC, NKI) in Genetics in Medicine. Zij evalueerden het rekenmodel onder ruim 8500 vrouwen.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/algoritme-kan-screening-borstkanker-verbeteren.htm	
35	In-vitro diagnostica	Risico	169	Lateral flow-tests feilbaar bij bepalen immuniteit covid-19	medisch contact	2-jul	later-flow test	09 Diagnostische laboratorium testen	later-flow test ongeschikt voor epidemiologische of medische besluitvorming	03 Waarschuwing/incident	Goede serologische tests zijn nodig om te bepalen hoe het staat met de immuniteit tegen covid-19 in de populatie. Maar zoals bekend zijn lang niet al die tests even betrouwbaar. De uitkomst van een studie door Mayara Lisboa Bastos e.a., gepubliceerd in The BMJ, onderstreept dat nog eens. Met name de lateral flow-tests, die internationaal veel gebruikt worden als point of care-tests, moeten het ontgelden.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/lateral-flow-tests-feilbaar-bij-bepalen-immuniteit-covid-19.htm	
35	Medische hulpmiddelen	Ontwikkeling	170	Uitzondering CE-markering blijft voor beschermingsmateriaal	medisch contact	12-aug	medische hulpmiddelen	20 Overig	CE-markering	12 Markttoelating	Vanaf 1 september moeten alle medische hulpmiddelen, behalve chirurgische mondkapjes, handschoenen en benodigdheden voor coronatesten, weer een CE-markering hebben. Sinds half maart was het in geval van nood toegestaan om medische hulpmiddelen zonder die markering te gebruiken en te leveren, maar dat is binnenkort voorbij, zo meldt de Inspectie Gezondheidszorg en Jeugd in een bericht op de eigen website. De medische hulpmiddelen zonder markering die zorgaanbieders al in huis hebben, mogen na 1 september ook niet meer worden gebruikt. Wel mogen de voorraden worden bewaard voor als er weer tekorten ontstaan bij een nieuwe golf van covid-19. Zorgaanbieders kunnen wel een ontheffing aanvragen voor specifieke medische hulpmiddelen.	https://www.medischcontact.nl/nieuws/laatste-nieuws/nieuwsartikel/uitzondering-ce-markering-blijft-voor-beschermingsmateriaal.htm	

35	In-vitro diagnostica	Ontwikkeling	171	Thermo Fisher builds $40M coronavirus test tube manufacturing facility in 6 weeks	FierceBiotech	31-aug	Toebehoren Coronatesten	09 Diagnostische laboratorium testen	Opschalen productie Coronatesten en toebehoren	06 Economisch nieuws	To help meet the relentless demand for COVID-19 diagnostics, Thermo Fisher Scientific has stood up a new, $40 million manufacturing facility in six weeks. The 120,000-square-foot plant at its Lenexa, Kansas site will be dedicated to producing viral transport media, the combination of buffering solution and plastic tubes that keep swab samples viable until they can be tested in the lab for the novel coronavirus.	https://www.fiercebiotech.com/medtech/thermo-fisher-builds-40m-coronavirus-test-tube-manufacturing-facility-6-weeks	
35	Implantaten	Ontwikkeling	172	Boston Sci's Lux-Dx Smart Implantable Arrhythmia Detector FDA Cleared	Medgadget	1-jul	Implanteerbare hartritmestoornis detector	02 Niet actief implantaat	FDA-toelating	12 Markttoelating	Boston Scientific has announced winning FDA clearance for its LUX-Dx Insertable Cardiac Monitor (ICM), an implant that can detect hard-to-spot cardiac arrhythmias, such as atrial fibrillation, and help diagnose their origin. The device's detection algorithm has two separate components, one of which detects a suspect arrhythmia and the other verifies the finding. Once an arrhythmia is confirmed, the wireless device sends a signal to the patient's cardiologist via an app installed on the patient's phone. Having a double-checking component within the implant's brains helps to prevent false positive alarms. To help cardiologists get the most out of the monitor, and as a side benefit during the ongoing COVID-19 pandemic, the LUX-Dx can be re-programmed by the physician remotely to adjust its arrhythmia detection settings. Other similar devices involve patients visiting their doctors for a change in programming to happen.	https://www.medgadget.com/2020/07/boston-scis-lux-dx-smart-implantable-arrhythmia-detector-fda-cleared.html	
35	Medische hulpmiddelen	Ontwikkeling	173	Reusable N95 Face Mask is Easily Sterilized	Medgadget	15-jul	Herbruikbaar n95 masker	20 Overig	Ontwikkeling herbruikbaar n95 masker van silicone	01 Nieuw product	Researchers at MIT and Brigham and Women's Hospital have developed an N95 face mask made from silicone rubber, which is reusable and is easily sterilized. The researchers hope that the mask could help with the response to the COVID-19 pandemic, as masks are in high demand and supplies are low. This group of researchers has developed an N95 mask that can be easily sterilized using a variety of methods, and safely reused. In doing so, they made sure that the masks could be produced at scale, using injection molding as the means of production. "One of the key things we recognized early on was that in order to help meet the demand, we needed to really restrict ourselves to methods that could scale," says Giovanni Traverso, a researcher involved in the study. "We also wanted to maximize the reusability of the system, and we wanted systems that could be sterilized in many different ways."	https://www.medgadget.com/2020/07/reusable-n95-face-mask-is-easily-sterilized.html	
35	Implantaten	Ontwikkeling	174	Edwards' KONECT RESILIA Aortic Valved Conduit Wins FDA Approval For Bio Bentalls	Medgadget	15-jul	Combinatie van aortaklep en aortagraft in 1 implantaat	02 Niet actief implantaat	FDA-toelating	12 Markttoelating	Edwards Lifesciences won FDA approval for its KONECT RESILIA aortic valved conduit, a device designed specifically for performing bio Bentall procedures. Typically, these complex surgeries require physicians to remove the aortic root, the aortic valve, and at least a part of the ascending aorta, and replace them with an artificial valve and an aortic graft that are sewn together. The KONECT RESILIA is essentially a prosthetic valve and an aortic graft in a single device, making it easier and faster to complete bio-Bentall procedures.	https://www.medgadget.com/2020/07/edwards-konect-resilia-aortic-valved-conduit-wins-fda-approval-for-bio-bentall-procedures.html	
35	Klinische technologie	Ontwikkeling	175	Vagus Nerve Stimulator Gets FDA Emergency OK for Asthmatics with COVID	Medgadget	27-jul	transcutane nervus vagus stimulator	20 Overig	FDA- emergency toelating	12 Markttoelating	People stricken with COVID-19 exhibit a wide range of symptoms. Some are barely affected while others suffer dire consequences. People with asthma are in particular danger, as SARS-CoV-2 is a respiratory virus that can make breathing even more difficult. Now, the FDA has issued an Emergency Use Authorization for the gammaCore Sapphire CV non-invasive vagus nerve stimulator (nVNS) to help adult asthmatics with COVID-19 (or those suspected of being infected) overcome difficulties breathing when drugs are not appropriate or are insufficient. The gammaCore stimulator has been approved as a treatment option for migraines and cluster headaches (see flashbacks below), but it was initially researched as a way for treating reactive airway diseases such as asthma. The new Emergency Use Authorization, in a way, validates that research. "Results from prior pilot studies that evaluated gammaCore for the acute treatment of asthma support our belief that nVNS may provide much needed relief to patients who are experiencing asthma-related breathing difficulty, which can be particularly debilitating in patients with COVID-19," said Peter Staats, MD, Chief Medical Officer of electroCore. Potentially this may lead to the vagus nerve stimulator being used more widely for asthma and other reactive airway diseases.	https://www.medgadget.com/2020/07/vagus-nerve-stimulator-gets-fda-emergency-ok-for-asthmatics-with-covid.html	
35	Klinische technologie	Ontwikkeling	176	TIGERTRIEVER XL Cleared in EU to Remove Large Stroke Clots	Medgadget	4-aug	Device om grote bloedproppen te verwijderen	12 Operatie instrument	CE-toelating	12 Markttoelating	Israel's Rapid Medical has won European regulatory clearance to introduce its TIGERTRIEVER XL device for removing large ischemic stroke-causing clots from intracranial vessels. The company calls its line of devices "stentrievers," as these look and operate similar to stents but can retrieve clots out of the body. Clot removed from the brain of the first stroke patient treated with Tigertriever XL at Bochum University Hospital The TIGERTRIEVER XL can be used to remove clots as big as 9 mm in diameter and 53 mm in length, all via a standard 0.02 internal diameter microcatheter. The company's CE marked TIGERTRIEVER 13 can go into arteries as narrow as 1 mm and there are stentrievers from Rapid Medical to cover all vessel sizes between the TIGERTRIEVER XL and TIGERTRIEVER 13.	https://www.medgadget.com/2020/08/tigertriever-xl-cleared-in-eu-to-remove-large-stroke-clots.html	

35	ICT, eHealth & Domotica	Ontwikkeling	177	NexStride Helps Overcome Freeze of Gait in Parkinson's	Medgadget	5-aug	Projector om 'freezes' tijdens het lopen van parkinson patienten te voorkomen	06 Wearables, incl sensoren op huid	Nieuw product	01 Nieuw product	People with Parkinson's disease and some other neurological disorders often suffer from a condition known as freezing of gait. For poorly understood reasons, initiating a step is often a challenge. Patients report a feeling of disassociation between one's will to move and the legs not responding accordingly. This is both frustrating and can lead to falls in many cases. With many neurological conditions, fooling the brain, by diverting attention and using other tricks, often works to alleviate symptoms. A new device is now available that utilizes intuitive visual and audio cues to help people with Parkinson's and similar conditions walk confidently with every step. The NexStride attaches to canes, walkers, and walking poles. A green laser generates a line ahead of the user's feet while a metronome clicks at a steady rate. The two effects work together to effectively prod the brain to move the legs deliberately and without hesitation. The green line gives users a target onto which to step, which is always there and always the same, while the beat seems to behave like a gentle nudge to get going	https://www.medgadget.com/2020/08/nexstride-helps-overcome-freeze-of-gait-in-parkinsons.html	
35	Medische hulpmiddelen	Ontwikkeling	178	LIONESS Device to Help Prevent Preterm Birth	Medgadget	6-aug	Device om cervix van zwangere vrouwen af te sluiten om vroeggeboorte te voorkomen	20 Overig	Nieuw product	02 Nieuwe therapie/techniek	Premature birth remains a huge clinical challenge, often resulting in lifelong consequences for both children and mothers. Even in developed nations, preterm birth is the most common cause of mortality for children under five years of age. In many cases, spontaneous onset of labor occurs and it is challenging to prevent this using current methods such as medications, surgery, or hormones. A company called PregnanTech out of Misgav, Israel has now designed an implantable device that reduces the load on the cervix, keeps the cervix elongated despite contractions, and thereby delays the biomechanical cascade and prevents the breakup of the collagen network that leads to spontaneous birth. The LIONESS, as it's called, is currently being tested in a clinical safety trial in women who are about to undergo hysterectomies. Next year the company plans to have its device trialed at King's College Hospital, London, in pregnant women at high risk of preterm birth	https://www.medgadget.com/2020/08/lioness-implant-to-help-prevent-preterm-birth.html	
35	Implantaten	Ontwikkeling	179	Endologix Alto Abdominal Stent Graft for AAA Cleared in Europe	Medgadget	6-aug	Abdominale aorta graft	02 Niet actief implantaat	CE-toelating	12 Markttoelating	Endologix, based in Irvine, California, won clearance in the European Union for its ALTO Abdominal Stent Graft System. The implant is intended to open up endovascular aortic repair to a wider range of abdominal aortic aneurysm (AAA) patients, particularly those with short and challenging aortic necks. Ideally, the aortic neck where the stent graft creates a seal is regular and smooth. In many cases, this is simply not so and a conventional mechanical seal doesn't work sufficiently. The ALTO features a novel polymer seal that seals tightly even irregularly shaped lumens, and which has been shown to keep a stable neck diameter five years post implantation, according to the company.	https://www.medgadget.com/2020/08/endologix-alto-abdominal-stent-graft-for-aaa-cleared-in-europe.html	
35	Klinische technologie	Ontwikkeling	180	Neurostimulation Device Reduces Withdrawal Symptoms of Kids Born Addicted to Opioids	Medgadget	11-aug	Neurostimulator om babies met opioden verslaving te ontwennen	20 Overig	uitbreiding patienten groep	02 Nieuwe therapie/techniek	Children born to mothers addicted to opioids suffer through withdrawal in their first few weeks of life. Morphine is commonly used in Neonatal Intensive Care Units (NICU) to alleviate symptoms while the kids are weaned from drug dependency. This typically takes two to four weeks, all the while the children are kept in the NICU. A new electrical device, called Roo from Spark Biomedical, is now undergoing testing, that may help shorten the weaning time to ten days or less by stimulating the cranial nerve branches on and near the ear. The therapy it administers, called Transcutaneous Auricular Neurostimulation (tAN), reportedly motivates the brain to release endorphins that bind to opioid receptors, and thereby reduce the brain's hunger for opioids. This technology was already successfully tested in a clinical trial on adult patients suffering from opioid withdrawal, so the same gentle-to-administer therapy was attempted with neonates as well. "This neurostimulation is giving the brain a little bit of a boost of its own endogenous opioids to perhaps reduce the need for exogenous morphine, which has all these dangerous side effects when delivered for prolonged periods of time in this critical neurodevelopmental window," said Bashar Badran, Ph.D., an assistant professor at Medical University of South Carolina (MUSC).	https://www.medgadget.com/2020/08/neurostimulation-device-reduces-withdrawal-symptoms-of-kids-born-addicted-to-opioids.html	
35	ICT, eHealth & Domotica	Ontwikkeling	181	Smartwatch Tracks Levels of Medication in the Body for Personalized Dosing	Medgadget	12-aug	Smartwatch om medicijnconcentraties te monitoren mbv zweet	06 Wearables, incl sensoren op huid	Nieuw product	01 Nieuw product	The watch works by stimulating sweat glands in the underlying skin through an electric current. The device can then analyze the sweat and can identify the electrochemical signature of specific drugs using a voltammetric sensing interface. The result is real-time continuous measurement of drug levels. "This technology is a game-changer and a significant step forward for realizing personalized medicine," said Ronald W. Davis, another researcher involved in the study. "Emerging pharmacogenomic solutions, which allow us to select drugs based on the genetic makeup of individuals, have already shown to be useful in improving the efficacy of treatments. So, in combination with our wearable solution, which helps us to optimize the drug dosages for each individual, we can now truly personalize our approaches to pharmacotherapy."	https://www.medgadget.com/2020/08/smartwatch-tracks-levels-of-medication-in-the-body-for-personalized-dosing.html	

35	In-vitro diagnostica	Risico	182	FDA flags accuracy issues with Thermo Fisher's COVID-19 test kit and software	FierceBiotech	18-aug	TaqPath kit	09 Diagnostische laboratorium testen	Problemen met Coronatest	03 Waarschuwing/incident	The FDA has flagged two issues with Thermo Fisher Scientific's molecular diagnostic for COVID-19 that could lead to inaccurate results. The company's TaqPath kit was one of the first commercial coronavirus tests granted an emergency authorization by the agency, in mid-March. Since then, the test has served as the basis for several COVID-19 diagnostics—including at-home sample collection kits developed by Rutgers University and P23 Labs, among other assays—and has been used with validated modifications. In an alert to clinical laboratory staff and healthcare providers, the agency pointed to insufficient mixing of samples linked to inadequate vortexing and centrifugation of the test's RT-PCR reaction plates, which can cause false positive results. Thermo Fisher has updated the kit's instructions to reduce the risk, affecting the test itself and any associated versions A second issue was traced to the assay's internal positive controls and the software used to interpret results on the company's Applied Biosystems instruments—which are also widely employed by other FDA-authorized coronavirus test kits. The agency recommended that lab staff promptly update the device's software to a newer version and complete a digital tutorial on its use as well as review the amplification curves for all positive results to determine whether a plate should be retested. The FDA also urged routine plate level checks to ensure accuracy.	https://www.fiercebiotech.com/medtech/fda-flags-accuracy-issues-thermo-fisher-s-covid-19-test-kit-and-software	https://www.mddionline.com/ivd/thermo-fishers-covid-19-test-could-have-inaccurate-results
35	Implantaten	Ontwikkeling	183	Medtronic's rechargeable neurostimulator implant nets FDA approval for bladder and bowel control	FierceBiotech	5-aug	InterStim Micro	01 Actief implantaat	Nieuw oplaadbare sacrale neurostimulator	01 Nieuw product	After receiving an FDA approval earlier this week for its newly miniaturized and rechargeable sacral nerve stimulator, Medtronic reported that its first patient has received the implant through the Cleveland Clinic, to help treat overactive bladder and fecal incontinence The InterStim Micro comes to the U.S. market months after its main competitor offered by Axonics Modulation Technologies, the r-SNM implant—which received its first FDA approval last September—but it's designed to be about half as small, with a volume of 2.3 cubic centimeters compared to Axonics' 5.5 cc.	https://www.fiercebiotech.com/medtech/medtronic-s-rechargeable-neurostimulator-implant-nets-fda-approval-for-bladder-and-bowel	https://www.mddionline.com/neurological/medtronic-ups-its-game-sacral-neuromodulation-bowel-and-bladder-control
35	In-vitro diagnostica	Ontwikkeling	184	FDA authorizes first tests for measuring COVID-19 antibody amounts	FierceBiotech	3-aug	Kwantitatieve bepaling van COVID-19 antilichamen	09 Diagnostische laboratorium testen	Kwantitatieve bepaling van COVID-19 antilichamen	01 Nieuw product	The FDA authorized its first serology tests designed to estimate the numbers of coronavirus antibodies in a person's bloodstream, instead of simply providing a positive or negative result on whether they are present. While it is still not known how long COVID-19 antibodies linger following an infection—or what levels may be necessary to provide protective immunity, and in what way—these tests can be used to identify people with a strong immune system response to the virus.	https://www.fiercebiotech.com/medtech/fda-authorizes-first-tests-for-measuring-covid-19-antibody-amounts	
35	Klinische technologie	Ontwikkeling	185	FDA clears ivWatch's IV safety monitoring sensor patch	FierceBiotech	10-jul	SmartTouch	20 Overig	Sensor die waarschuwt bij lekkage tijdens toediening van IV-vloeistoffen	02 Nieuwe therapie/techniek	The FDA cleared a miniaturized and disposable sensor patch designed to detect early complications from IV drug infusions—including potentially harmful leaks of medication into the surrounding tissue, such as from a misplaced needle. Available for all ages, ivWatch's SmartTouch device tapes over the infusion site to continuously monitor for escaping IV fluids under the skin, and is designed to alert caregivers hours before they can be detected by sight or touch. Using an optical sensor, the patch is capable of detecting fluid infiltrations of about 2 milliliters or less. ivWatch previously developed a larger, FDA-cleared peripheral IV monitor that measures a person's tissue fluid volume changes, and attaches to a patient's IV pole.	https://www.fiercebiotech.com/medtech/fda-clears-ivwatch-s-iv-safety-monitoring-sensor-patch	
35	Systeem	Risico	186	Image by Tierney - Adobe Stock COVID-19 Medical Device Shortages and What the Industry Is Doing About It	MDDI	17-aug	FDA lijst met tekorten producten door COVID-19	20 Overig	FDA lijst met tekorten producten door COVID-19	11 Overig	FDA maintains a publicly-available, up-to-date list of the medical device shortages tied to the pandemic. This list is part of FDA's obligation under the CARES Act, which was signed into law on March 27. Of the 20 products that FDA listed on Friday, eight are categorized as testing supplies and equipment, nine are considered personal protective equipment, and three are ventilation-related products. The testing-related shortages include: Clinical sample concentrator; Transport culture medium; Sterile swabs; microbiological specimen collection and transport devices; instrumentation for clinical multiplex test systems; real time nucleic acid amplification system; general purpose reagents for in vitro diagnostic tests; and microbial nucleic acid storage and stabilization devices.	https://www.mddionline.com/covid-19/covid-19-medical-device-shortages-and-what-industry-doing-about-it	
35	Implantaten	Risico	187	Transcatheter tricuspid valve replacement "low risk" for complications	CardioVascular News	18-aug	transkatheter tricuspedaalklep	02 Niet actief implantaat	minder complicaties	11 Overig	Transcatheter tricuspid valve replacement in the setting of trans-tricuspid pacemaker leads without extraction or re-replacement can be performed safely with a low risk of complications, a study published in JACC: Cardiovascular Interventions has found. The study, authored by Jason H Anderson (Mayo Clinic, Rochester, USA) and colleagues, concludes that transcatheter valve replacement for valve-in-valve or valve-in-ring implantation offers a safe alternative to surgical valve replacement in the setting of pacemaker leads.	https://cardiovascularnews.com/transcatheter-tricuspid-valve-replacement-low-risk-for-complications/	
35	Systeem	Ontwikkeling	188	European MDCG sets deployment date for Eudamed actor registration module	Emergo	26-aug	Eudamed	16 Wet en regelgeving	registratie economic operators	05 Standaardisatie, wet-/regelgeving/NoBo	The European Medical Device Coordinating Group (MDCG) has set a deployment date for an important component of the Eudamed database for registration of economic operators.	https://www.emergobyul.com/blog/2020/08/european-mdcg-sets-deployment-date-eudamed-actor-registration-module	
35	Implantaten	Risico	189	Risk of Loss of Coordination in Parkinson's Patients with Deep Brain Stimulators	FDA	30-jul	Deep brain stimulator	01 Actief implantaat	Coordinatieverlies bij diepe hersenstimulator	03 Waarschuwing/incident	The U.S. Food and Drug Administration would like to remind patients and health care providers about a potential safety risk associated with the use of deep brain stimulation (DBS) devices for the treatment of Parkinson's Disease. Specifically, patients with DBS devices may experience a loss of coordination during water-related activities such as swimming.	https://www.fda.gov/medical-devices/safety-communications/risk-loss-coordination-during-water-related-activities-parkinsons-patients-deep-brain-stimulators	
35	Implantaten	Risico	190	FDA In Brief: FDA Posts Interim Results from Required Essure Postmarket Surveillance Study	FDA	8-jul	Essure	02 Niet actief implantaat	Interim results of PMS study	11 Overig	The U.S. Food and Drug Administration (FDA) posted an update with the interim results from the Essure Postmarket Surveillance ("522") Study. Although Essure is no longer being manufactured or distributed, the FDA continues to monitor the safety profile of the device through an FDA-required postmarket surveillance study.	https://www.fda.gov/news-events/fda-brief/fda-brief-fda-posts-interim-results-required-essure-postmarket-surveillance-study	

35	Klinische technologie	Ontwikkeling	191	Enrolment initiated in world's first RCT with sirolimus-coated balloon for below-the-knee PAD treatment	Interventional News	27-aug	Magic Touch PTA Sirolimus-coated Balloon	20 Overig	RCT drug-coated balloon catheter	11 Overig	Concept Medical has announced the enrolment of the first patient in the FUTURE BTK (Randomised controlled trial of first sirolimus coated balloon versus standard balloon angioplasty in the treatment of below-the-knee artery disease) trial. The index patient was successfully enrolled on 26 August 2020 in Singapore.	https://interventionalnews.com/enrolment-initiated-in-future-btk-trial/	
35	Implantaten	Ontwikkeling	192	Endologix Initiates Chapter 11 and is Set to Go Private	MDDI	6-jul	Nellix Endovascular Aneurysm Sealing System	02 Niet actief implantaat	Faillissement	06 Economisch nieuws	By going through bankruptcy, the Irvine, CA-based company is expected to eliminate about $180 million of debt from its balance sheet. For the past few years, Endologix has struggled with regulatory issues tied to the Nellix EndoVascular Aneurysm Sealing System. Endologix has initiated Chapter 11 bankruptcy and has entered into an agreement with Deerfield Partners, its largest creditor, to be taken private.	https://www.mddionline.com/covid-19/endologix-initiates-chapter-11-and-set-go-private	
35	Implantaten	Ontwikkeling	193	Implantaat tegen tinnitus lijkt te werken, zonder het gehoor aan te tasten	Nederlands Dagblad	20-aug	auditory brainstem implant	01 Actief implantaat	implantaat tegen tinnitus	01 Nieuw product	Het implantaat, dat door middel van een operatie ingebracht moet worden in de hersenstam, wordt een auditory brainstem implant (ABI) genoemd. Uit voorlopige resultaten blijkt het tinnitus te verminderen zónder het gehoor aan te tasten.	https://www.nd.nl/nieuws/nederland/988306/implantaat-lijkt-te-werken-tegen-tinnitus	
35	ICT, eHealth & Domotica	Ontwikkeling	194	App voor huidkanker voorkomt duizenden huisartsbezoeken	skipr	8-sep	huidkanker app	04 App	huidkanker app	11 Overig	CZ is tevreden over de app Skinvision en biedt deze dienst ook komend jaar gratis aan voor de eigen verzekerden. Uit nieuwe cijfers blijkt dat de app duizenden foto's van verdachte plekjes op de huid heeft beoordeeld. In de overgrote meerderheid van de gevallen was een bezoek aan de huisarts niet nodig.	https://www.skipr.nl/nieuws/app-voor-huidkanker-voorkomt-duizenden-huisartsbezoeken/	
35	Medische hulpmiddelen	Ontwikkeling	195	Nederlandse ziekenhuizen gaan operatieafval hergebruiken	skipr	4-sep	disposables	20 Overig	hergebruik disposables	11 Overig	Afvalrecycler Renewi en GreenCycl starten volgende maand een proef om afval van de operatiekamers en sterilisatieafdelingen in een aantal Nederlandse ziekenhuizen beter te circuleren. Dat kan de kosten voor instrumentarium fors verminderen.	https://www.skipr.nl/nieuws/nederlandse-ziekenhuizen-gaan-operatieafval-hergebruiken/	
35	ICT, eHealth & Domotica	Ontwikkeling	196	Antonius lanceert botbreuk-app om polibezoek te voorkomen	skipr	28-aug	botbreuk app	04 App	botbreukk app	11 Overig	Een nieuwe app voorkomt dat patiënten met botbreuken voor controle terug moeten naar de poli van het St. Antonius Ziekenhuis. Met de Virtuel Fracture Care app kunnen patiënten thuis aan hun herstel werken.	https://www.skipr.nl/nieuws/antonius-lanceert-botbreuk-app-om-polibezoek-te-voorkomen/	
35	Klinische technologie	Ontwikkeling	197	Utrechtse bioprinter print razendsnel lichaamsdelen	Zorg & ICT	8-sep	3D-printer	14 3D printer/product	3D-printer	02 Nieuwe therapie/techniek	Onderzoekers van de Universiteit Utrecht en het UMC Utrecht (UMC) ontwikkelen een 3d-printer die binnen enkele minuten een deel van het menselijk lichaam kan namaken, inclusief levende cellen. Daarmee wordt het mogelijk individuele modellen van delen van een patiënt te maken, bijvoorbeeld om buiten het lichaam geneesmiddelen te testen.	https://www.zorg-en-ict.nl/newsitem/26339	

Vakgroep	
ICT, eHealth & Domotica	Cybersecurity, zorgportalen, elektronische patiënten dossiers (EPD's), wearables (smart watch, google glasses), exoskeletons, apps en software als medisch hulpmiddel
Implantaten	Niet-actieve: orthopedische implantaten (heup, knie), reconstructieve en cosmetische implantaten (borstimplantaten, rimpelvullers, bekkenbodemmatjes), vasculaire implantaten (stents), implantaten voor maag/darm/lever/alvleesklier/urinewegen. Actieve implantaten (o.a. pacemaker, neurostimulatoren, bionisch oog)
In-vitro diagnostica	Genetische testen, laboratorium testen, zelftest (zwangerschapstest), (continue) bloedglucosemeter, POCT (Point-Of-Care test, gebruikt door zorgverleners), producten waar gebruikt wordt gemaakt van een IVD in combinatie met een App (mobiele telefoon) tbv diagnose of monitoring, analyse apparatuur voor diagnostiek .
Klinische technologie	Apparatuur in ziekenhuis zoals beademingsapparatuur, nierdialyseapparatuur (kunstnier), infuusapparaten, operatierobot, MRI, röntgenapparatuur, endoscopen, bronchoscopen (beeldvormende technieken). (elektromedische apparatuur voor behandeling of diagnose, straling), maar ook bijv. de kunstmatige alvleesklier (is buiten lichaam voor monitoring en toedienen van medicatie), nieuwe operatie methodes/behandelmethodes, 3D printeR (dus niet het geprinte implantaat -> implantaten)
Medische hulpmiddelen	Pleisters, naalden, gehoortoestel, ziekenhuisbed, operatie instrumenten (mes, pincet) (her)sterilisatie en reiniging, dentale producten, oogheelkundige producten, zelfzorgmiddelen, thuis- en verpleegzorg technologie, klasse 1 medische hulpmiddelen, prothese
Systeem	Wet en regelgeving medische hulpmiddelen, normen, nieuwe richtlijnen.

Ontwikkeling of risico
Ontwikkeling
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Vrije invulvelden	
Product	**Onderwerp**
naam van product (bijv. Laser of als bekend de merknaam + naam fabrikant)	Wat is de belangrijkste boodschap van het bericht benoemen: in enkele kernwoorden
voorbeeld: ultrasoonproductapparaat	versnellen wondheling
voorbeeld: ehealth applicatie	effecten op zorg, kosten, etc.
voorbeeld: digitale zorg	meer innovatie in zorg door digitale zorg

Product categorie	
01 Actief implantaat	bv. pacemaker, neurostimulator
02 Niet actief implantaat	bv. Heup, borst, knie
03 Prothese/exoskeleton	bv. buiten lichaam zoals kunstbeen
04 App	voor mobiel, tablet
05 EPD/ patiëntgegevens	medische data
06 Wearables, incl sensoren op huid	Smart watch, bloeddrukmeter etc
07 Overig ICT	Software/hardware, etc
08 POC test/zelftest	POC test = voor zorgverleners
09 Diagnostische laboratorium testen	Testen uit te voeren in ziekenhuis labs
10 Robotica	Alle type robotten (chirurgisch, bloedafname, revalidatie etc)
11 Beeldvormende/bestralings technieken	MRI, CT, PET, echo, bestraling van kankerpatienten
12 Operatie instrument	Messen, tangen etc
13 Scopen & camera's	Bv endoscopen
14 3D printer/product	
15 Oogheelkundig hulpmiddel	Contactlenzen, bionisch oog, lenzen vloeistof, oogmeetapparatuur
16 Wet en regelgeving	
17 Augmented/virtual reality	Live beeld van de werkelijkheid waaraan elementen worden toegevoegd door een computer. Bv anatomische structuren in de patient op de operatietafel die met een VR bril zichtbaar worden voor de chirurg.
18 Artificial intelligence	Computersysteem dat grote hoeveelheden gegevens kan verwerken en analyseren om daarmee tot een diagnose te komen
19 Dentaal/orthodontie	
20 Overig	

Onderwerp categorie	
01 Nieuw product	
02 Nieuwe therapie/techniek	
03 Waarschuwing/incident	
04 Recall	Product van de markt gehaald
05 Standaardisatie, wet-/regelgeving/NoBo	NoBo = Notified Bodies
06 Economisch nieuws	Overname, investering, rechtszaak, dingen voor goedkopere zorg
07 Counterfeit/illegaal	Vervalste medische hulpmiddelen, medische hulpmiddelen zonder CE markering op de markt
08 Cybersecurity/hacken	
09 Training/skills lab/opleiding	
10 Nieuwe ontwikkeling	Nieuwe ontwikkeling die niet is in te delen in de eerste 9 categorieën hierboven
11 Overig	Bijv. ~~A~~lgoritme om ziekte te voorspellen, combiproduct mhm en geneesmiddel, ethisch aspect.
12 Markttoelating	Markttoelating van een medisch hulpmiddel, bijv. door FDA 510K clearance of CE mark

Criteria	
Impact (intensitiet en omvang)	van invloed voor veel mensen (patienten)
	van invloed voor weinig mensen (patienten)
Beleids- en maatschappelijk relevant	ja
	nee
Binnen 10 jaar actueel	ja
	nee
Realiteitsgehalte en nieuwswaarde	bericht van onafhankelijke bron
	actueel
	acuut/terugkerend risico
	ernstig probleem