IV Essential Requirements Check List

No.	GENERAL REQUIREMENTS	Apply	Standards, Directive, etc	Documents of evidence
1	The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.	Yes	EN ISO 13485:2016 EN ISO 14971:2019 EN 62366-1:2015	Quality System EN ISO 13485: 2016 Risk Management Report Design History File Risk analysis was conducted and is documented in the Risk Analysis Reports located in the Design History Files. Usability Evaluation
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction) - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that can not be eliminated. - inform users of the residual risks due to shortcomings of the protection measures adopted.	Yes	EN ISO 13485:2016 EN ISO 14971:2019 EN 13641:2002 EN 62366-1:2015	Quality System EN ISO 13485: 2016 Risk Management Report Design History File Risk Management Report History Files. Usability Evaluation
3.	The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2)(b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and	Yes	EN ISO 13485:2016 EN 62366-1:2015 EN ISO15223-1：2016 EN ISO18113-1:2011 EN ISO 18113-4:2011 EN 13612:2002 EN ISO 23640:2015	Quality System EN ISO 13485: 2016 Design History File The performance characteristics were developed. This documentation is located in the Design History Files Usability Evaluation Product Performance Report Stability Studies Report

	limits of detection, stated by the manufacturer. The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.			
4.	The characteristics and performance referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patients or the user and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.	Yes	EN ISO 13485:2016 EN ISO15223-1：2016 EN ISO18113-1:2011 EN ISO 18113-4:2011 EN 13612:2002 EN 23640:2015 EN ISO 14971:2019 EN 62366-1:2015 EN ISO 23640:2015	Quality System EN ISO 13485: 2016 Design History File Risk Management Report History Files. The performance characteristics were developed. This documentation is located in the Design History Files Usability Evaluation Product Performance Report Stability Studies Report
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage (temperature, humidity, etc.) taking into account the instructions and information provided by the manufacturer.	Yes	EN ISO 13485:2016 EN ISO15223-1：2016 EN ISO18113-1:2011 EN ISO 18113-4:2011 EN 13612:2002 EN ISO 14971:2019 EN ISO 23640:2015	Quality System EN ISO 13485: 2016 Risk Management Report Design History File Usability Evaluation Product Performance Report Stability Studies Report
	DESIGN & MANUFACTURING REQUIREMENTS			
1. 1.1	Chemical and Physical The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in Section A on the "General Requirements". Particular attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials and the specimens (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.	Yes	EN ISO 13485:2016 EN ISO 18113-4:2011 EN 13612:2002 EN ISO 14971:2019 EN ISO 23640:2015	Quality System EN ISO 13485: 2016 Risk Management Report Design History File Usability Evaluation Product Performance Report Stability Studies Report
1.2	The devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the	Yes	EN ISO 13485:2016 EN ISO 18113-4:2011 EN 13641:2002 EN ISO 14971:2019 EN ISO 23640:2015	Risk Management Report Design History File Usability Evaluation Product Performance Report

	product.			Stability Studies Report
2. 2.1	Infection and microbial contamination The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.	Yes	EN ISO 13485:2016 EN ISO 14971:2019 EN 13641:2002	Quality System EN ISO 13485: 2016 Risk Management Report Design History File
2.2	Where a device incorporates biological substances, the risks of infection must be reduced as far as possible by selecting appropriate donors and appropriate substances and by using appropriate validated inactivation, conservation, test and control procedures.	Yes	EN 13641:2002	Risk Management Report Design History File
2.3	Devices labelled either as 'STERILE' or as having a special microbiological state must be designed, manufactured and packed in an appropriate pack, according to procedures suitable for ensuring that they remain in the appropriate microbiological state indicated on the label when placed on the market, under the storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened.	N.A	The devices listed are not sterile and do not have a special microbiological state	N.A
2.4	Devices labelled either as 'STERILE' or as having a special microbiological state must have been processed by an appropriate, validated method.	N.A	The devices listed are not sterile and do not have a special microbiological state	N.A
2.5	Packaging systems for devices other than those referred to in section 2.3 must keep the product without deterioration at the level of cleanliness indicated by the manufacturer and, if the devices are to be sterilised prior to use, reduce as far as possible the risk of microbial contamination. Steps must be taken to reduce as far as possible microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.	Yes	EN 13641:2002 EN ISO 14971:2019 EN 13612:2002 EN ISO 23640:2015	Processing management procedure Risk Management Report History Files Usability Evaluation Product Performance Report Stability Studies Report

2.6	Devices intended to be sterilized, must be manufactured in appropriately controlled (e.g. environmental) conditions.	N.A	The devices listed are not intended to be sterile	N.A
2.7	Packaging systems for non-sterile devices must keep the product without deterioration in the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Yes	EN ISO 14971:2019 EN 13641:2002 EN ISO 23640:2015	Risk Management Report Product and process inspection and measurement procedure
3 3.1	Manufacturing and environmental properties If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on the use must be indicated on the label or in the instructions for use.	N.A	The device is not used in combination with other devices or equipment.	N.A
3.2	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks linked to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use	Yes	EN ISO 14971:2019 EN 13641:2002	Quality System EN ISO 13485: 2016 Risk Management Report Design History Files
3.3	Devices must be designed and manufactured in such a way as to remove or reduce as far as possible: — the risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, ergonomic features), — risks linked to reasonably foreseeable external influences, such as magnetic fields, external electrical effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of substances into the device. Devices must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity of electromagnetic disturbance to enable them to operate as intended.	Yes	EN ISO 14971:2019 EN 13641:2002	Risk Management Report Design History Files
3.4	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of fire or explosion during normal use and in single fault condition.	N.A	There are no explosive or fire risks associated with these devices	N.A

	Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
3.5	Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.	N.A	There are no special disposal requirements for these devices	N.A
3.6	The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.	Yes	EN 13612:2002 EN ISO 23640:2015	Usability Evaluation Product Performance Report Stability Studies Report
4 4.1	Devices which are instruments or apparatus with measuring function Devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.	N.A	These devices are not instruments and/or apparatus with measuring functions	N.A
4.2	When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement.	N.A	These devices are not instruments and/or apparatus with measuring functions	N.A
5 5.1	Protection against radiation Devices shall be designed, manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimised.	N.A	There is no radiation or radiation hazards associated with the devices	N.A
5.2	When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be: — designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted,	N.A	There is no radiation or radiation hazards associated with the devices	N.A

	— fitted with visual displays and/or audible warnings of such emissions.			
5.3	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.	N.A	There is no radiation or radiation hazards associated with the devices	N.A
6 6.1	Requirements for medical devices connected to or equipped with an energy source Devices incorporating electronic programmable systems, including software, must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.	N.A	The devices are not connected to or equipped with an energy source	N.A
6.2	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.	N.A	The devices are not connected to or equipped with an energy source	N.A
6.3	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained correctly.	N.A	The devices are not connected to or equipped with an energy source	N.A
6.4 6.4.1	Protection against mechanical and thermal risks Devices must be designed and manufactured in such a way as to protect the user against mechanical risks. Devices must be sufficiently stable under the foreseen operating conditions. They must be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected life of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated. Any guards or other means included with the device to provide protection, in particular against moving parts, must be secure and must not interfere with access for the	N.A	There are no mechanical or thermal risks associated with the devices	N.A

	normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.			
6.4.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	N.A	There are no vibrations risks associated with the devices	N.A
6.4.3	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	N.A	There are no noise risks associated with the devices	N.A
6.4.4	Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimise all possible risks.	N.A	There are no connections to electricity, gas or hydraulic or pneumatic energy supplies associated with the devices	N.A
6.4.5	Accessible parts of the devices (excluding the parts of areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	N.A	There are no thermal risks associated with the devices	N.A
7	Requirements for devices for self-testing Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.	Yes	EN ISO 14971:2019 EN 62366-1:2015	Risk Management Report Design History File Risk analysis was conducted and is documented in the Risk Analysis Reports located in the Design History Files. Usability Evaluation Lay person study report
7.1	Devices for self-testing must be designed and manufactured in such a way as to: — ensure that the device is easy to use by the intended lay user at all stages of the procedure, and — reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the	Yes	EN ISO 14971:2019 EN 62366-1:2015	Risk Management Report Design History File Risk analysis was conducted and is documented in the Risk Analysis Reports located in the Design History Files. Usability Evaluation Lay person study report

	results.			
7.2	Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.	Yes	EN ISO 14971:2019 EN 62366-1:2015	Labelling: Label Instruction for Use Usability Evaluation Lay person study report
8 8.1	Information supplied by the manufacturer Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the data on the label and in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices. Instructions for use must accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used properly and safely without them. The decision whether to translate the instructions for use and the label into one or more languages of the European Union shall be left to the Member States, except that, for devices for self-testing, The instructions for use and the label must include a translation into the official	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use Translation SOP and protocol

	language(s) of the Member State in which the device for self-testing reaches its final user.			
8.2	Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labeling: Label Instruction for Use
8.3	In the case of devices containing a substance or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC and Directive 88/379/EEC shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use. The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.	N.A	The devices listed do not contain any substances or preparations considered as dangerous	N.A
8.4 8.4 (a)	The label must bear the following particulars which may take the form of symbols as appropriate: The name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the Package Insert shall contain in addition the name and address of the authorised representative of the manufacturer;	Yes	EN ISO 13485:2016 EN ISO15223-1：2016 EN ISO18113-1:2011 EN ISO 18113-4:2011	Labelling: Label Manufacturer and Authorized Representative information is located on the side or bottom flap of the kit box
8.4 (b)	The details strictly necessary for the user to uniquely identify the device and the contents of the packaging;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011	Labelling: Labe The name of the product is clearly marked on the front of the kit box. The contents of the packaging are listed on the rear or side flap of the kit box
8.4 (c)	Where appropriate, the word 'STERILE' or a statement indicating any special microbiological state or state of	N.A	The device is not sterile	N.A

	cleanliness;			
8.4 (d)	The batch code, preceded by the word 'LOT", or the serial number;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label The batch number is listed next to the harmonized symbol "LOT" (Batch code)
8.4 (e)	If necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011	Labelling: Label Test The expiration date is listed next to the harmonized symbol for "USE BY"
8.4 (f)	In case of devices for performance evaluation, the words 'for performance evaluation only';	No	This device is not intended for performance evaluation	N.A
8.4 (g)	Where appropriate, a statement indicating the in vitro use of the device;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use The harmonized symbol for "IN VITRO DIAGNOSTIC USE ONLY" is located on the front of each kit box
8.4 (h)	Any particular storage and/or handling conditions;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use The harmonized symbol for "TEMPERATURE LIMITATION" is located on the front or rear panel of each box
8.4 (i)	Where applicable, any particular operating instructions;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use The harmonized symbol for "CONSULT INSTRUCTIONS FOR USE" refers users to the Package Insert where the operating instructions are provided
8.4 (j)	Appropriate warnings and/or precautions to take;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use The harmonized symbol for "CONSULT INSTRUCTIONS FOR USE" refers users to the

				Package Insert where the precautions are listed
8.4 (k)	If the device is intended for self-testing, that fact must be clearly stated.	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use
8.5	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label The intended use is defined in the upper left corner of the package insert under heading
8.6	Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO 14971:2019	Labelling: Label Instruction for Use The information that allows users to detect any potential risk is defined in the section labelled "PRECAUTIONS" Identification and Traceability Management Procedure
8.7 8.7 (a)	Where appropriate, the Package Insert must contain the following particulars: The details referred to in section 8.4 with the exception of points d) and e);	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use Manufacturer and Authorized Representative Information are listed in the lower right corner of the Package Insert. The name of the product is clearly listed in the upper left corner of the Package Insert. The intended use is listed in italics in the upper left hand corner of the package insert above the heading "PRINCIPLE"
8.7 (b)	Composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use Reagent composition is listed in the section labelled "REAGENTS" an" MATERIALS SUPPLIED"
8.7 (c)	The storage conditions and shelf life following the first opening of the primary container, together with the		EN ISO18113-1:2011	Labelling: Label Instruction for Use

	storage conditions and stability of working reagents;	Yes	EN ISO 18113-4:2011 EN ISO15223-1：2016	Storage and handling information is listed in the section labelled "STORAGE AND STABILITY".
8.7 (d)	The performances referred to in section 3 of part A;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use Performance characteristics are listed in the "PERFORMANCE CHARACTERISTICS" section.
8.7 (e)	An indication of any special equipment required including information necessary for the identification of that special equipment for proper use;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use Equipment essential for proper use of this device are outlined in the sections labelled "MATERIALS REQUIRED BUT NOT PROVIDED", if any.
8.7 (f)	The type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use Specimen type is listed in the "INTENDED USE" sections.
8.7 (g)	A detailed description of the procedure to be followed in using the device;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use Detailed description of the procedure to be followed is listed on the Package Insert under the section labelled "TEST PROCEDURE".
8.7 (h)	The measurement procedure to be followed with the device including as appropriate: — the principle of the method, — the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitations of the method and information about the use of available reference measurement procedures and materials by the user, — the details of any further procedure or handling needed before the device can be used (for example, reconstitution, incubation, dilution, instrument checks,	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use The principle of the method is described in the "PRINCIPLE" sections. The specific performance characteristics are listed in the "PERFORMANCE CHARACTERISTICS" section. The limitations of the method are listed in the "LIMITATIONS". Further handling before the device can be used is described in the section labelled "PRECAUTIONS". No special training is required to use this device, and therefore no indication of required training is included on the Package Insert.

	etc.), — the indication whether any particular training is required;			
8.7 (i)	The mathematical approach upon which the calculation of the analytical result is made;	N.A	The devices listed do not incorporate a mathematical approach or calculation to provide a quantitative result. The device is for qualitative measurement only.	N.A
8.7 (j)	Measures to be taken in the event of changes in the analytical performance of the device;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Instruction for Use Measures to be taken due to changes in analytical performance are described in the "LIMITATIONS" section.
8.7 (k)	Information appropriate to users on: — internal quality control including specific validation procedures, — the traceability of the calibration of the device;	No	The internal quality control is not included in the package insert to the user. The devices listed do not require calibration, and therefore no such information is provided to the user.	N.A
8.7 (l)	The reference intervals for the quantities being determined, including a description of the appropriate reference population;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use The reference interval and associated information is listed in the section labelled "Questions And Answers"
8.7 (m)	If the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination;	N.A	The devices listed are not used in combination with or installed with any other medical devices.	N.A
8.7 (n)	All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use The information needed to verify whether the device is working properly is included in the test and is described in the section labelled "PRINCIPLE". The device does not require calibration or maintenance. Safety waste disposal is included in the "PRECAUTIONS" section.
8.7	Details of any further treatment or handling needed	N.A	The device can be used directly	

(o)	before the device can be used (for example, sterilisation, final assembly, etc.);			
8.7 (p)	The necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilisation or decontamination;	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use Necessary instructions in the event of damage to the packaging are listed in the "PRECAUTIONS" section.
8.7 (q)	If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilisation or decontamination, and any restriction on the number of reuses;	No	The devices listed are intended for single use only.	Instruction for Use The harmonized symbol for "DO NOT REUSE" is located at the lower right corner of the package insert.
8.7 (r)	Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	N.A	The devices listed are not susceptible to such environmental conditions.	N.A
8.7 (s)	Precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;	Yes	EN ISO15223-1：2016 EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO 18113-4:2011 EN ISO 14971:2019 EN 13641:2002	Instruction for Use Safe disposal of device is recommended in the section labelled "PRECAUTIONS"
8.7 (t)	Specifications for devices for self-testing: — the results need to be expressed and presented in a way that is readily understood by a lay person; information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result, — specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device, — the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner, — the information must also specify that when the device for self-testing is used for the monitoring of an existing	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Labelling: Label Instruction for Use

	disease, the patient should only adapt the treatment if he has received the appropriate training to do so;			
8.7 (u)	Date of issue or latest revision of the instructions for use.	Yes	EN ISO18113-1:2011 EN ISO 18113-4:2011 EN ISO15223-1：2016	Instruction for Use Date of issue and revision number is located in the lower right corner of the Package Insert.

Approved by: ____5.1.2e 5.1.2e_____ Date: 2020.09.03

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