Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

MLS N.V.

concerning the supply of

Syringes and (safety) needles

contract number 5.1.1c

5.1.2e

Content

Annexes

[redacted]

The undersigned

The **State of the Netherlands**, represented by his Minister of Public Health, Welfare and Sport, on behalf of the Minister represented by 5.1.2e of the National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu) **(RIVM),** having his home office at Antonie van Leeuwenhoeklaan 9, 3721 MA Bilthoven, the Netherlands,

hereinafter referred to as "**Purchaser"**

and

MLS N.V., having his office at Ringlaan 7, B-8930 Menen, Belgium, duly represented b 5.1.2e 5.1.2e

hereinafter referred to as **"Supplier"**,

whereas

Purchaser acts as the exclusive procurement agency under order of the Ministry of Health, Welfare and Sport (VWS) for syringes and safety needles.

Purchaser desires to purchase syringes and (safety) needles for the agreed upon quantity and timelines as specified below in this contract to be used for the immunisation or treatment of people against Covid-19 or any other diseases.

Supplier has offered to to deliver the requested syringes and (safety) needles.

now therefore the parties have agreed as follows:

1. Definitions

In this Contract, the following terms shall be interpreted as indicated:

"Affiliate" means, with respect to each party, any entity which directly or indirectly through one or more intermediaries: (i) has Control over such party; (ii) is under Control of such party; (iii) is under Control of any of (i) or (ii); or (iv) is under common Control with such party, from time to time.

"Contract" means the agreement entered into between Purchaser and Supplier, as defined in the contract signed by the parties, including all Annexes thereto and all documents incorporated by reference therein.

"Contract Price" means the price per product of the Goods payable to Supplier under the Contract for the full and proper performance of the contractual obligations.

"Control" means, as to any entity: (i) direct or indirect ownership of at least fifty percent (50%) on a fully diluted basis of the voting and/or economic interests in the entity in question; or (ii) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the entity in question (whether or not exercised and whether through ownership of securities or other ownership interests, by contract or otherwise).

"Days" means calendar days.

"Force Majeure" means any circumstance or event beyond a party's reasonable control which prevents or delays the performance of any of that party's obligations under this Agreement including (to the extent not of that party's making nor capable of prevention or mitigation by contingency planning): (i) earthquake, storms, flood and other acts of nature, war, riots, hostility (whether or not war has been declared), terrorist acts, acts of any civil or military authority, public disturbance or (ii) any strike, lock-out or other industrial trade dispute (other than in each case by the personnel or other employees, contractors, suppliers or agents of the party seeking to rely on the Force Majeure).

"Goods" means all following products: 5.1.1c 5.1.1c and necessary documents to be supplied by Supplier, as specified in Annex 1 Product Specifications of the Contract.

"Intellectual Property Rights" or "IP" means all rights, title and interest in patents, copyright (including rights in computer software and moral rights), right in inventions, trade marks (and the right to sue for passing off), service marks, rights in designs (whether or not protected by copyright), utility models, service marks, database rights and rights in data, domain names, trade names, logos, rights in get up, trade secrets and rights in know-how, whether or not any of these rights are registered or unregistered and shall include applications for any such right, matter or registration thereof and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of these rights which may subsist anywhere in the world.

"Party" means either Purchaser or Supplier.

2. Supply of the Goods

2.1 Supplier agrees to supply to Purchaser and Purchaser agrees to purchase from Supplier the Goods in accordance with the provisions of the Contract and in accordance with the conditions and specifications stated in the Annex 1 Product Specifications.
Purchaser desires to purchase:

5.1.1c

volume to be delivered in at most 2 deliveries, as specified in Annex 1e.

Supplier guarantees that the offered Sol-Care safety needles can also be effectively attached and used with the 5.1.1c from Becton, Dickinson as confirmed in Annex 1f .

The packaging of the Goods are specified in Annex 1 (number of products per item per pack, number of packs per transportation carton and number of transportation cartons per EU pallet (shall not exceed 5.1.1c .
The syringes and safety needles have a CE-mark and must comply with the essential requirements of the MDD 93/42/EEC. Manufacturers must have a quality management system that complies with the standard ISO 13485 or FDA 21 CFR 820.
The syringes and safety needles shall have a remaining shelf life after delivery to the RIVM of at least 48 (fourty-eight) months. 5.1.2b number is allowed.

3. Delivery

3.1 All Goods shall be delivered by Supplier in accordance with the Incoterms 2010 ICC Delivery Duty Paid, to:

Movianto
Keltenweg 70
5342LP OSS

3.2 Supplier shall deliver 5.1.2b of the Goods firmly ordered pursuant to this Contract on the delivery date agreed by the parties in writing.

3.3 If at any time during performance of the Contract, Supplier should encounter conditions impeding timely delivery of the Goods and/or documents, Supplier shall promptly notify Purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as possible after receipt of Supplier's notice, the parties shall agree on a revised delivery time for the Goods and/or documents.

4. Packaging, labelling and documentation

4.1 All Goods shall be packed, labelled, marked and handled in accordance with the specifications laid down in Annex 1.

5. Guarantees and liability

5.1 Supplier guarantees that (i) the delivered Goods (including the documents and packaging material) are in conformity with the Contract at the time of delivery, (ii) the delivered Goods at the time of delivery are in conformity with the agreed specifications laid down in Annex 1 and any approved reference samples, (iii) the Goods do not infringe any rights of third parties and (iv) that the Goods at the time of delivery are free from defects, including at any rate errors in the design, material, sterility and manufacture, and comply with all applicable statutory rules and regulations.

5.2 All Goods shall have a remaining shelf life after delivery to RIVM of at least 48 months.
The expiry date must be shown on the product, packaging, on the Certificate of Conformity and on the batch release certificate. Products supplied with insufficient shelf life shall be subject to free of charge replacement.

5.3 If the Goods are not in conformity with the Contract, Purchaser may, at his discretion, require

that the Goods be repaired or replaced free of charge, or that the purchase price be reimbursed, without prejudice to Purchaser's other rights under this Contract or by law. If the aforementioned lack of conformity results in additional efforts by Purchaser and/or the executing third parties, the costs of these additional efforts will be fully compensated by Supplier.

5.4 Purchaser may return Goods that are not in conformity with the Contract at Suppliers costs until Supplier has issued further instructions as to what should be done with the Goods. Any reasonable costs to be incurred by Purchaser in returning the Goods will be for Suppliers account. Purchaser will be responsible for storage of the Goods before they are returned to Supplier.

5.5 Supplier shall assume full responsibility and shall indemnify Purchaser from all direct losses, liabilities, claims, costs, direct damages and expenses resulting from the Goods supplied. Excluded are any and all damage(s) resulting from loss of profit, loss of contracts, loss of reputation, loss of management or employee productivity, increase in legal feesor any other form of indirect loss, including consequential loss ('gevolgschade'). Supplier shall further indemnify Purchaser from all direct losses, liabilities, claims, costs, direct damages and expenses resulting from the Goods supplied, incurred by claims - in connection with the Goods under this Contract - of third parties. Excluded are any and all damage(s) resulting from loss of profit, loss of contracts, loss of reputation, loss of management or employee productivity, increase in legal fees or any other form of indirect loss, including consequentlial loss ('gevolgschade'). Purchaser will not be able to rely on this indemnification clause if the damages concerned are the result of actions on the part of Purchaser. The liability per event is limited to an amount of 5.1.2b and the amount of the total liability will be capped at 5.1.2b However, this limitation of liability does not apply: in the event of third-party claims for compensation resulting from death or injury and/or in the event of intent or gross negligence on the part of the Supplier or his Staff.

5.6 Supplier shall have and maintain an insurance of 5.1.2b euros) against any damage incurred by Purchaser as a consequence of Suppliers failure to perform any of his obligations, or as a consequence of a wrongful act committed against Purchaser or a third party. The insurance shall amongst others cover product liability. Supplier shall provide Purchaser the relevant insurance certificate. Supplier shall inform Purchaser immediately and without any delay when there are changes (to be expected) regarding the relevant insurance certificate.

5.7 If at any time Purchaser decides to recall the Goods due to the fact that the Goods do not comply with the Contract or for any other sound reason, Purchaser shall notify Supplier in writing immediately. Parties will then follow the recall procedure set forth in the Quality Agreement (Annex 2 Quality Agreement). Purchaser's right to demand redelivery of defective Goods is regulated in Section 5.3 of the Contract. Supplier shall indemnify Purchaser for any reasonable and documented costs resulting from or connected with the product recall due to Supplier's negligence, acts or ommissions in performing its obligations under this Contract up to a maximum of 5.1.2b For the avoidance of doubt, Purchaser will not be able to rely on this indemnification clause if such third party claims are the result of actions or negligence on the part of Purchaser.

6. Industrial and intellectual property rights

6.1 Supplier shall indemnify Purchaser against all direct loss or direct damage (including reasonable legal costs) incurred by Purchaser as a result of any claim that the possession, distribution and/or use of the Goods, made available to Purchaser under this Agreement, infringes or are alleged to infringe the intellectual property rights of any third party up to a maximum of 5.1.2b 5.1.2b percent of the Contract Price of the delivered Goods which infringes or are alleged to infringe the intellectual property rights of any third party.

6.2 Neither party shall use the other party's name or any other identifying name of that party or any of its Affiliates for advertising, referral, publicity or other similar purposes or attach such

names or members of that party or other identity to any goods or include it in any publication (including any publication in electronic media) without the other party's prior written consent, which shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, Parties agree that they each may prepare, circulate and issue general internal and external communications and/or press releases, which may also be posted on social media, to inform internal and external stakeholders and audiences about the existence of the Contract mentioning the products, the contracted volumes without, however, disclosing any confidential information, including but not limited to the Contract Price, delivery schedule, payment terms and conditions, liability, etc..

7. Audits and inspections

7.1 Supplier agrees that Purchaser or his duly authorised representatives have the right to audit the premises where the products are manufactured and stored on the basis of the ISO 13485 standard/ FDA 21 CRF 820 and the MDD 93/42 directive.

7.2 These audits will be scheduled to be mutually convenient to both parties. Corrective and preventive actions resulting from the observations during the inspection have to be performed in the soonest possible way. Supplier shall bear all costs resulting from aforementioned agreed upon corrective and preventive actions. Supplier will report to Purchaser about his efforts in the carrying out of the corrective and preventive actions within a laid down time frame.

8. Prices

8.1 The Contract Price per product for the Goods to be supplied under the Contract is fixed for all Goods supplied and is as follows in Euro excl. VAT:

5.1.1c

8.2 The Contract Prices mentioned in article 8.1 should include delivery on a DDP basis to Oss, or another place within the Netherlands specified by RIVM.

8.3 The Contract Price, as specified and stated in article 8.1, is fixed until December 31st, 2021. For the following 12 (twelve) Monthly Period a new Contract Price may be proposed by Supplier using solely an indexation on the Contract Price. Such a proposal needs to be made minimum 6 (six) months before December 31st, 2021. Purchaser has to agree in writing with the proposed Contract Prices, before it is fixed for the following 12 (twelve) Monthly Period. This indexation will be based on the Dutch "consumentenprijsindex (CPI), totaal bestedingen 2020 = 100").

The following calculation method applies:
(CPI index (new month (e.g. May 2021)) - CPI index (old month (e.g. May 2020))) / CPI index (old month) * 100%.

9. Payment and documents

9.1 Each shipment has to be accepted by Purchaser's QP Department by signing the Certificate of Payment (Annex 3 Certificate of Payment). This Certificate of Payment will be sent to Supplier after the acceptance of the delivery by Purchaser's QP Department.

9.2 Supplier will prepare proper electronic invoices and will send the invoices and the signed Certificate of Payment digitally to Purchaser. Invoices will only be processed by RIVM if they have been submitted electronically in XML format to RIVM via one of the ways mentioned on www.tradeinterop.com/rivm-en and if the purchase order number of RIVM to which the invoice

relates, is stated on the invoice. Supplier will receive the instructions to be followed from the Purchaser.

All consequences, due to delay in forwarding the documents to Purchaser, will be for Supplier's account.

9.3 Only invoices with a signed Certificate of Payment will be approved. Within 30 (thirty) Days Purchaser shall effect payment of the approved invoices.

10. Confidentiality

10.1 In connection with the Contract, Supplier and Purchaser (as to information disclosed, the Disclosing Party) may each provide the other Party (as to information received, the Receiving Party) with Confidential Information. Confidential Information is all commercial and technical information and knowledge acquired in the performance of the Contract (including commercial terms). The Receiving Party agrees not to disclose any Confidential Information and shall use Confidential Information only for the purpose intended by the Contract. Each Party shall obligate his employees and his advisors to respect said confidentiality. The obligations of the Parties under this section shall survive the termination of the Contract regardless of the manner of such termination.

10.2 The foregoing obligation shall not apply to any information which:

- was known and can be shown to be known to the Receiving Party prior to the time it was received;
- was known to the public or generally available to the public prior to the time it was received;
- becomes known to the public or generally available to the public without the Receiving Party being responsible thereof;
- was received at any time from a third party who, to the knowledge of the Receiving Party, is under no obligation to maintain the confidentiality of such information;
- was independently developed by the Receiving Party and can be shown to have been so developed by contemporaneous written records;
- has to be disclosed due to applicable laws or regulations or a court or administrative order.

11. Assignment and sub-contracts

11.1 Supplier shall not assign, in whole or in part, his obligations to perform under the Contract, except with Purchaser's prior written consent. However, Supplier may assign this Contract and all rights and obligations hereunder to any wholly-owned subsidiary or to any successor bymerger or sale of substantially all of its assets to which this Contract relates.

11.2 Subject to clause 11.1, Supplier shall notify Purchaser in writing of all sub-contracts awarded under the Contract if not already agreed upon in writing by the parties. Such notification, in his original bid or later, shall not relieve Supplier from any liability or obligation under the Contract or under the law.

12. Contract amendments

12.1 No variation in or modification of the terms of the Contract shall be made except by written amendment signed by both parties.

13. Review clause (conform Directive 2014/24/EU, article 72)

13.1 Purchaser is in any case able to change the Contract during the term if the following conditions apply:

a. VWS decides to change the implementation of the Covid-19 vaccination programme; and

b. as a result, the number of the Goods conform article 2.1 of the Contract, will proportionally (pro rata) increase with the number of doses that is related to the decision of VWS.

13.2 Purchaser is also able to change the Contract during the term if the following conditions apply:
a) The average vaccination uptake of Covid-19 vaccination programme increases to 85% or higher; and
b) as a result, the number of doses of the Goods conform article 2.1 of the Contract, will proportionally (pro rata) increase with the number of doses that is related to the current vaccination uptake.

13.3 The financial consequence of a change as referred to in paragraphs 13.1 and 13.2 will be worked out between Parties to come to an appropriate solution.

13.4 The delivery schedule (conform Annex 1) will be adjusted as a result of a change as referred to in paragraphs 13.1 and 13.2 in good consultation between both parties, whereby at least a delivery period of 6 (six) months is observed.

13.5 Supplier and Purchaser agree to a change as referred to in paragraphs 13.1 and 13.2 in writing in accordance with article 12 of this Contract.

14. Annexes

14.1 The following Annexes form an integral part of the Contract:

Annex 1 Product Specifications
Annex 1a
Annex 1b
SN2310 5.1.1c
Annex 1c
Annex 1d
Annex 1e Delivery Schedule
Annex 1f Statement
Annex 2 Quality Technical Agreement
Annex 3 Certificate of Payment
Annex 4 Communication table

15. Term and termination

15.1 This Contract will enter into force on October 1th, 2020 and will remain in force for a period of 18 months.

15.2 Purchaser will at any point in time be entitled to suspend payment or terminate this Contract, except for (iv) for which a notice period of 3 (three) weeks will be applicable, if;
(i) any Goods made available by Supplier to Purchaser become subject to attachment;
(ii) Supplier is granted a suspension of payments or is declared bankrupt provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to Purchaser;
(iii) any permits or certificates are withdrawn required for Supplier's performance of the Contract;
(iv) Supplier is in material breach with one or more of his obligations ensuing from this Contract, provided that if the default is remediable, Supplier fails to remedy the default within 3 (three) weeks of being sent a default letter stating the default and the required performance. For the sake of clarity, Supplier's decision pursuant to clause 6.3 to not replace non-conformity Goods but instead repair or reimburse the Purchase the contract price of these, shall not be considered a breach of an obligation under this Contract;
(v) Supplier ceases his business.

The above provisions will not detract from Purchasers right to compensation of any and all losses and expenses ensuing from Suppliers failure to perform or from his anticipated failure to perform.

Supplier will at any point in time be entitled to suspend delivery of Goods to Purchaser and/or terminate this Contract, with a notice period of three (3) weeks, if;

(i) Purchaser is in material breach with one or more of his obligations ensuing from this Contract, provided that if the default is remediable, Purchaser fails to remedy the default within 3 (three) weeks of being sent a default letter stating the default and the required performance;

(ii) any permits or certificates are withdrawn required for Purchaser's performance of the Contract.

15.3 Neither Party shall be liable to, or deemed to be in default to, the other Party for a delay in performing or for a failure to perform its obligations under this Contract to the extent that and for as long as the delay or failure results from an event of Force Majeure. The Party affected by the Force Majeure shall immediately give notice to the other Party and shall use all reasonable endeavours to mitigate the effects of the Force Majeure on the performance of its obligations under this Contract.

15.4 In the event any case of Force Majeure will continue for a period of more than 2 (two) months, Parties are entitled to terminate the Contract by giving 30 (thirty) days prior written notice, without owing any compensation whatsoever with respect hereto.

15.5 Obligations which by their nature are intended to persist after the Contract has been terminated or performed will remain in force after the expiry of the Contract. These obligations include the provisions on: guarantee, non-performance, liability, termination, documentation, assignment of insurance proceeds, confidentiality and disputes and applicable law.

16. Resolution of disputes

16.1 Purchaser and Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

16.2 A dispute exists if either of the two Parties makes an allegation to this effect. In any dispute regarding the concluding, the interpretation or execution of this Contract or any other dispute with respect to, or in connection with, this Contract, the parties shall within a period of 2 (two) months (starting from the moment one Party gives notice to the other Party that there is a dispute), exhaust all possible means to arrive at an amicable solution. If they are unable to do so, the dispute shall be submitted to the judgment of the competent court in The Hague, The Netherlands

17. Notices

All notices and other communications shall be in the form of a document, including, for the avoidance of doubt, an electronic mail message.

The notice and other communications should be addressed in conformance with Annex 4.

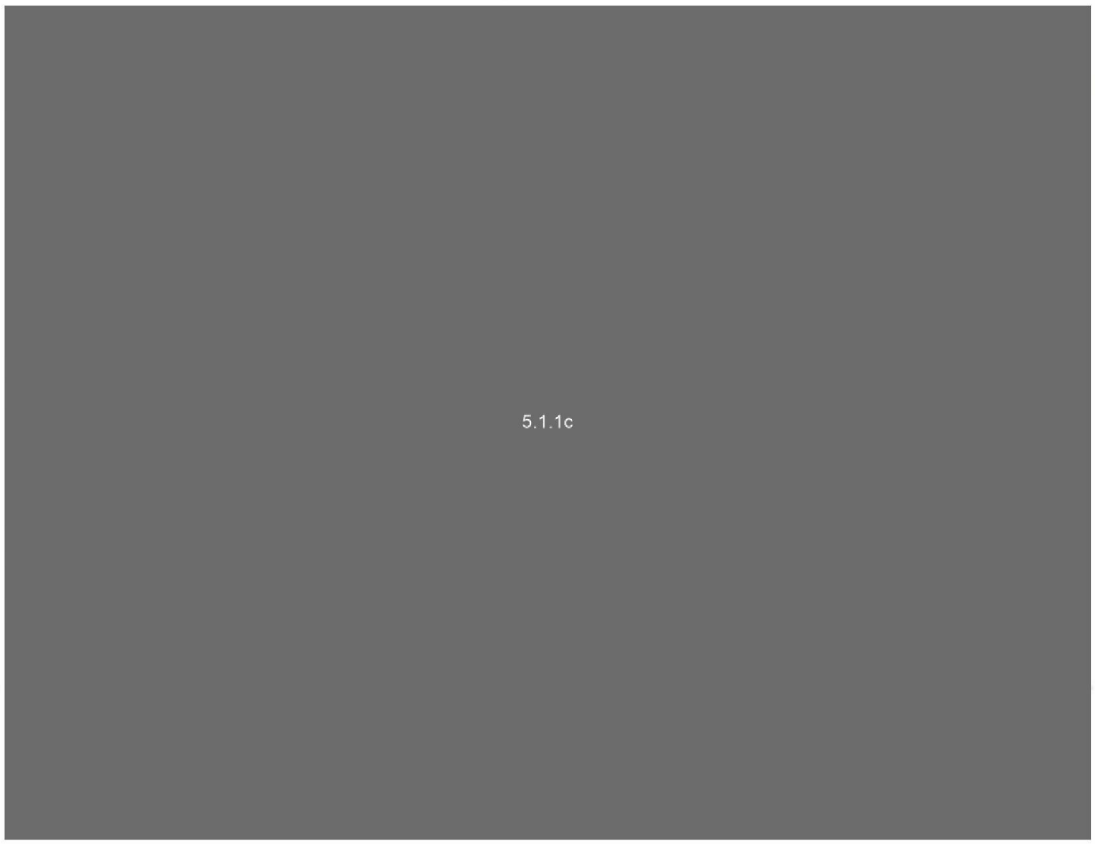
18. Governing language

18.1 All contract documents, all communications and documents related to the Contract shall be in the English language.

19. Applicable law

19.1 This Contract and the relationship under it between the parties shall be governed by, and interpreted in accordance with, the Laws of the Netherlands. The UN Convention on Contract for the International Sale of Goods (CISG) is not applicable to this Contract.

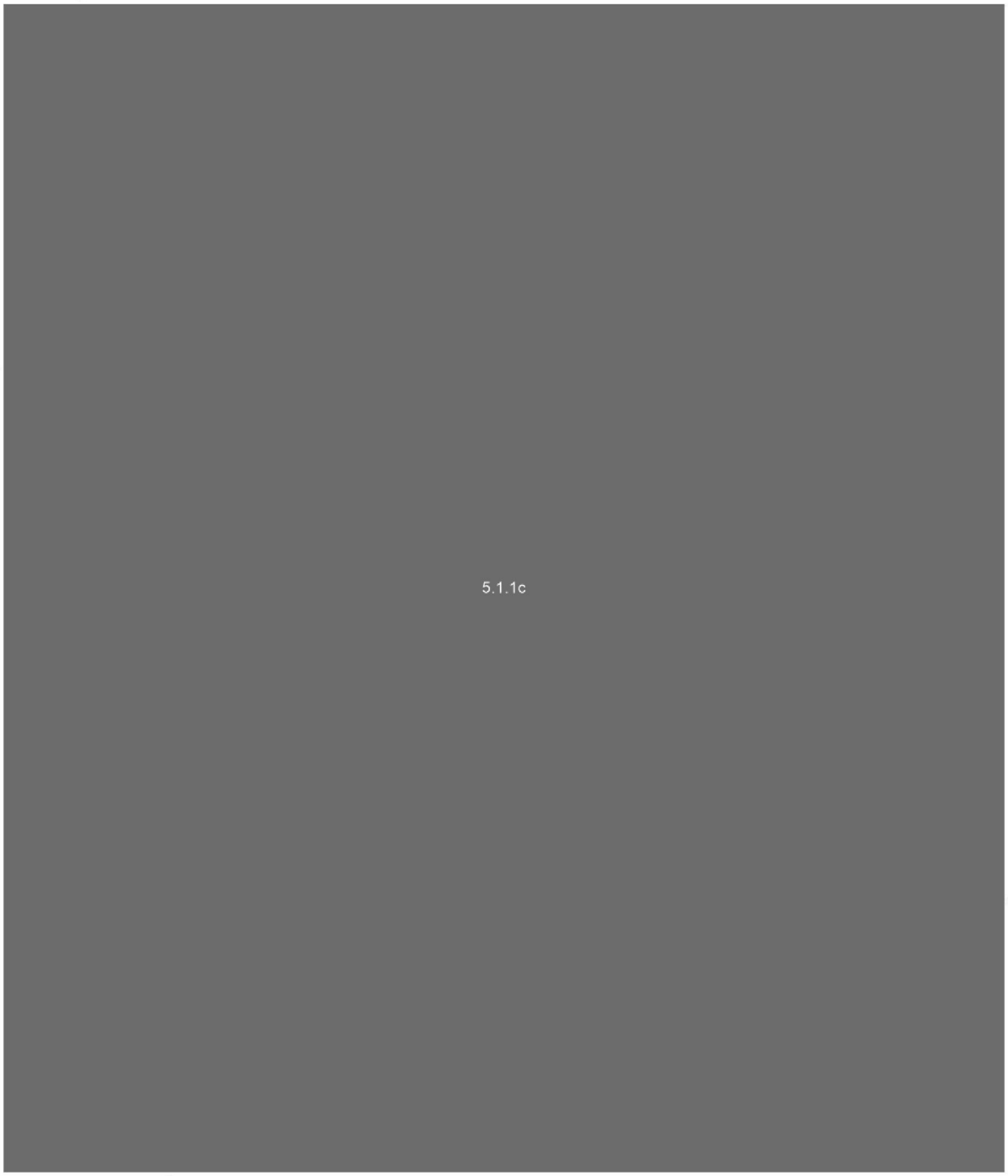
Annex 1 Product Specifications



The transport and storage conditions for all above products :
Room temperature. Keep dry, keep away form sunlight.

Documents:

Batch certificate	Yes
Certificate of Conformity per batch	Yes
Certificate of Transport Release (CoTR)	Yes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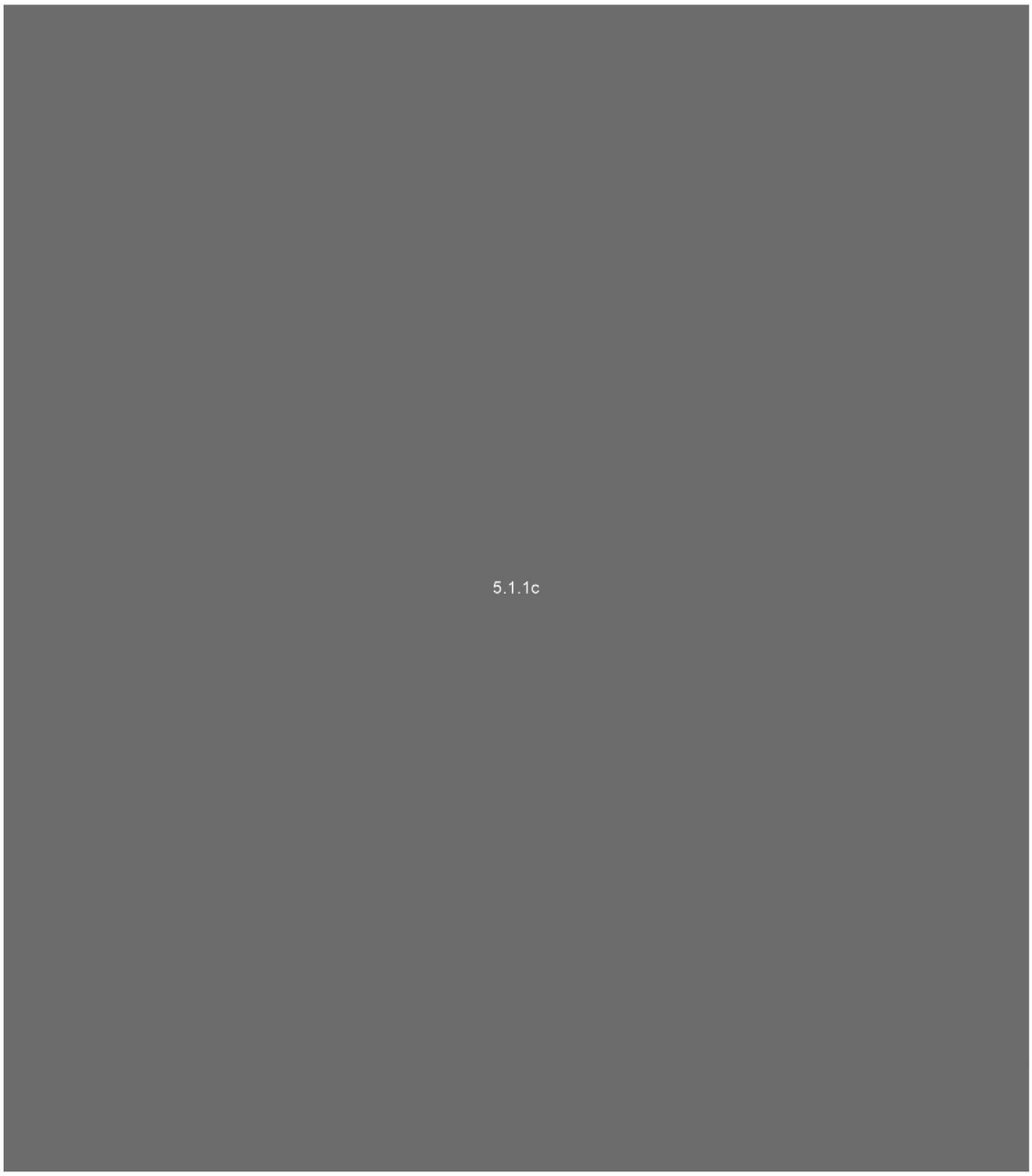
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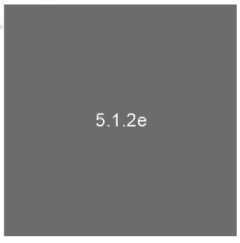
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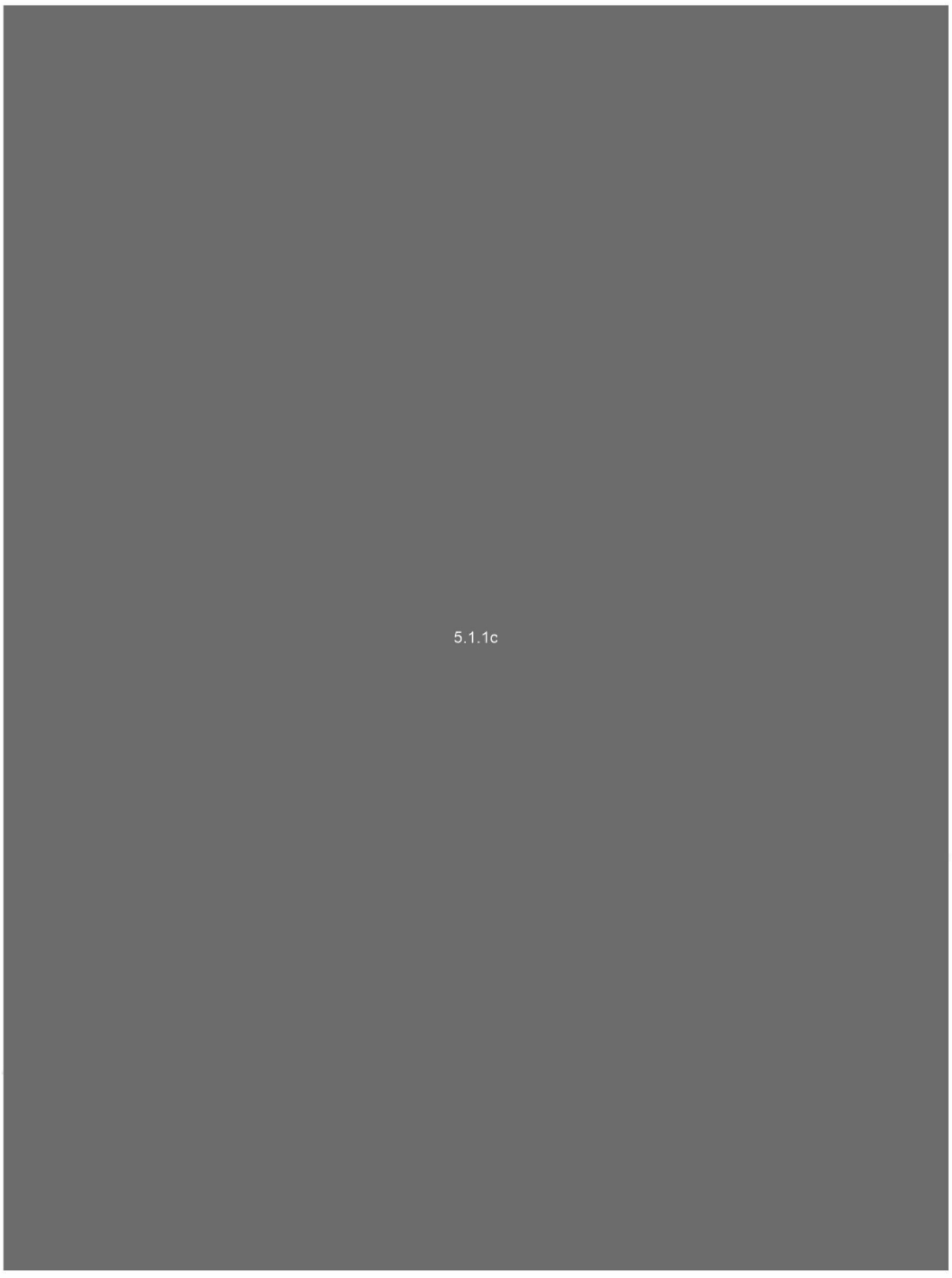
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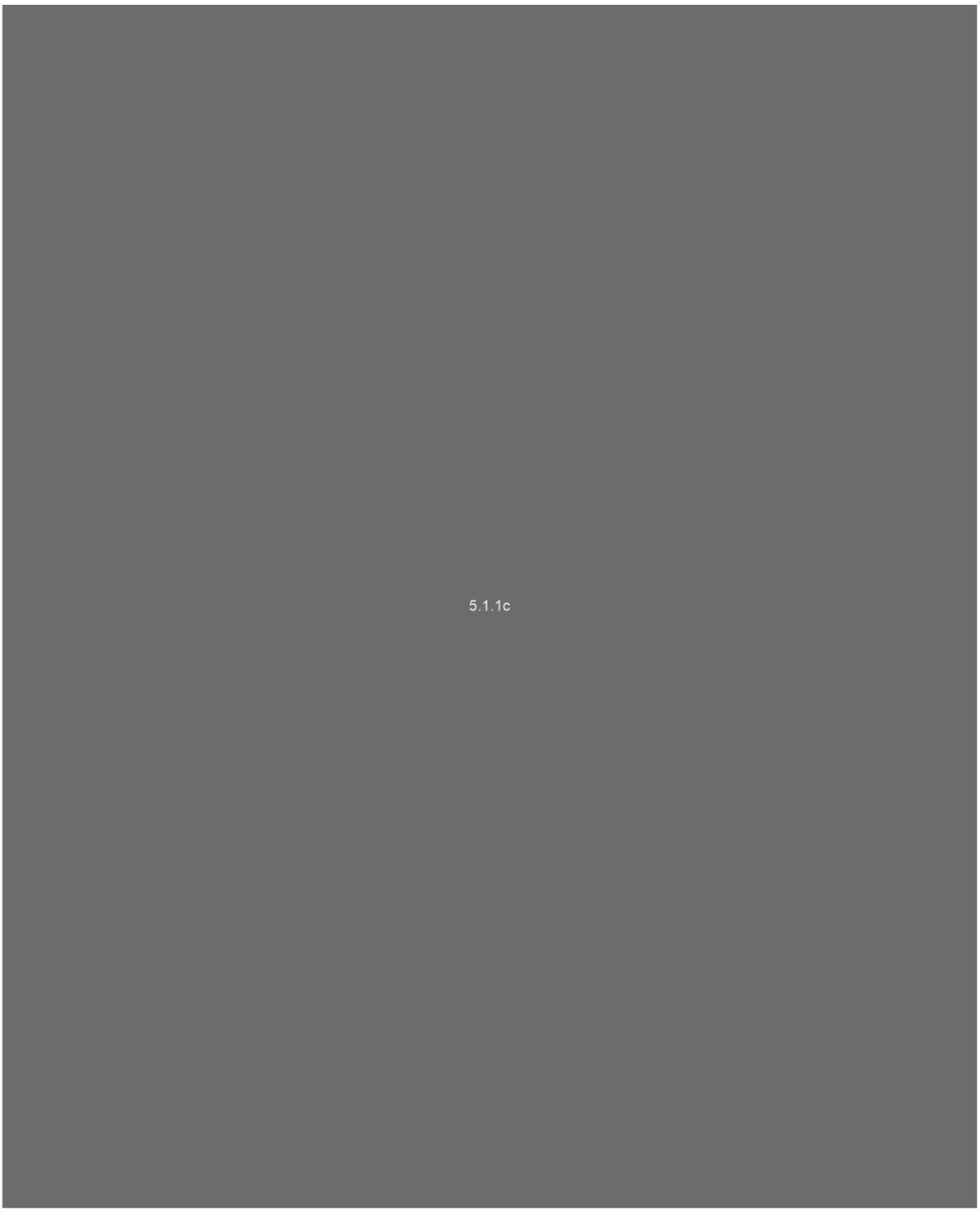
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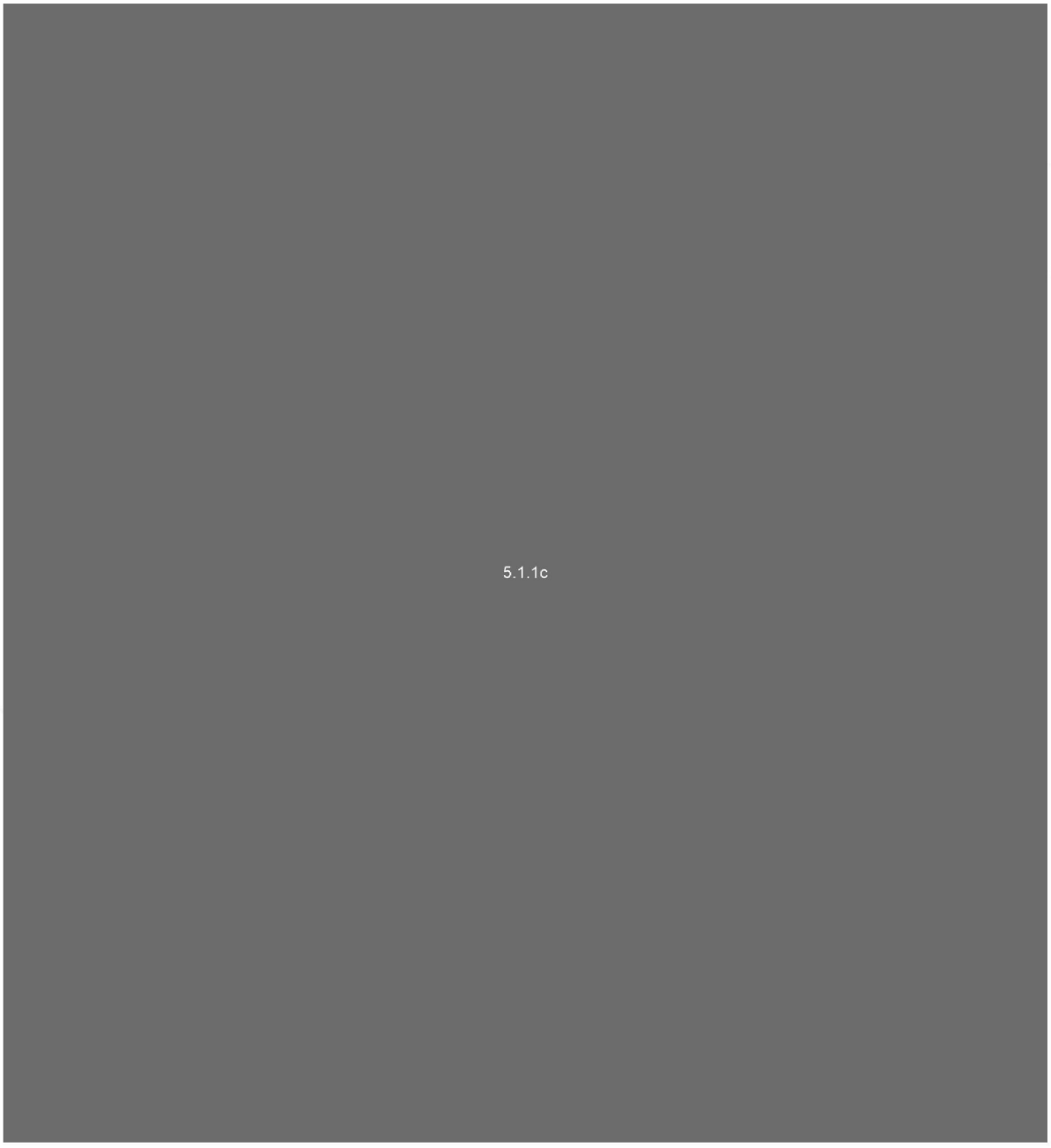
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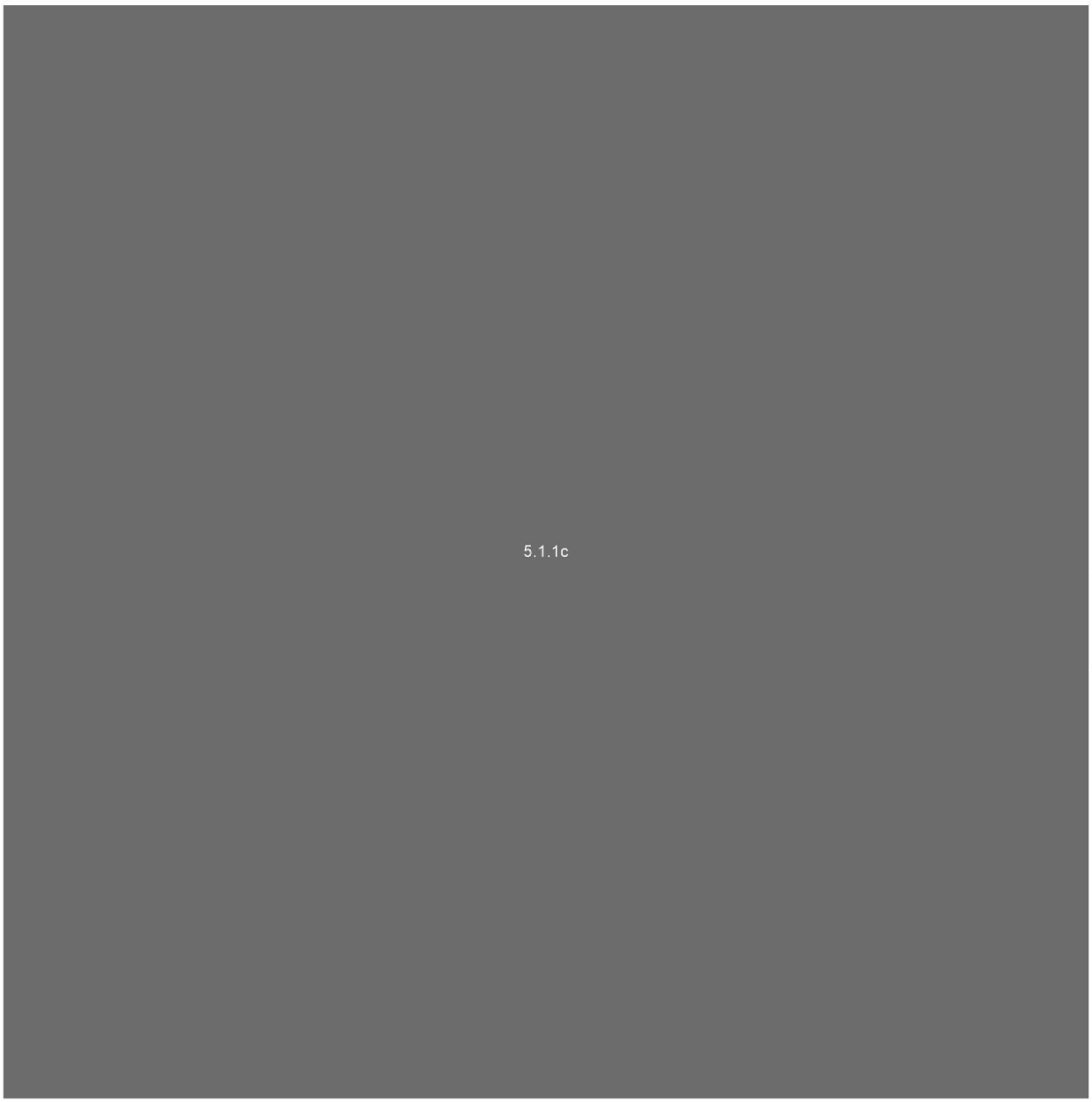
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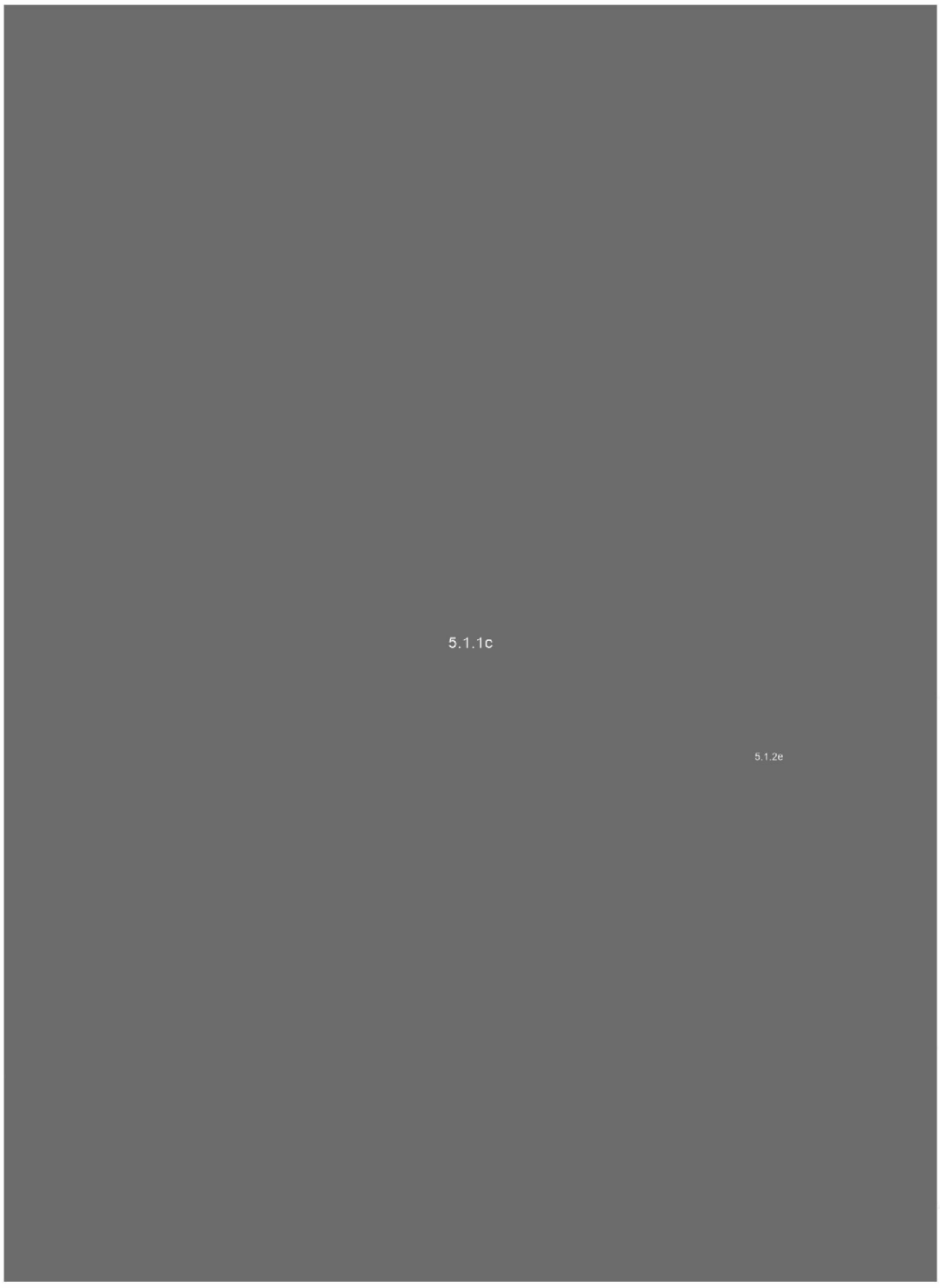
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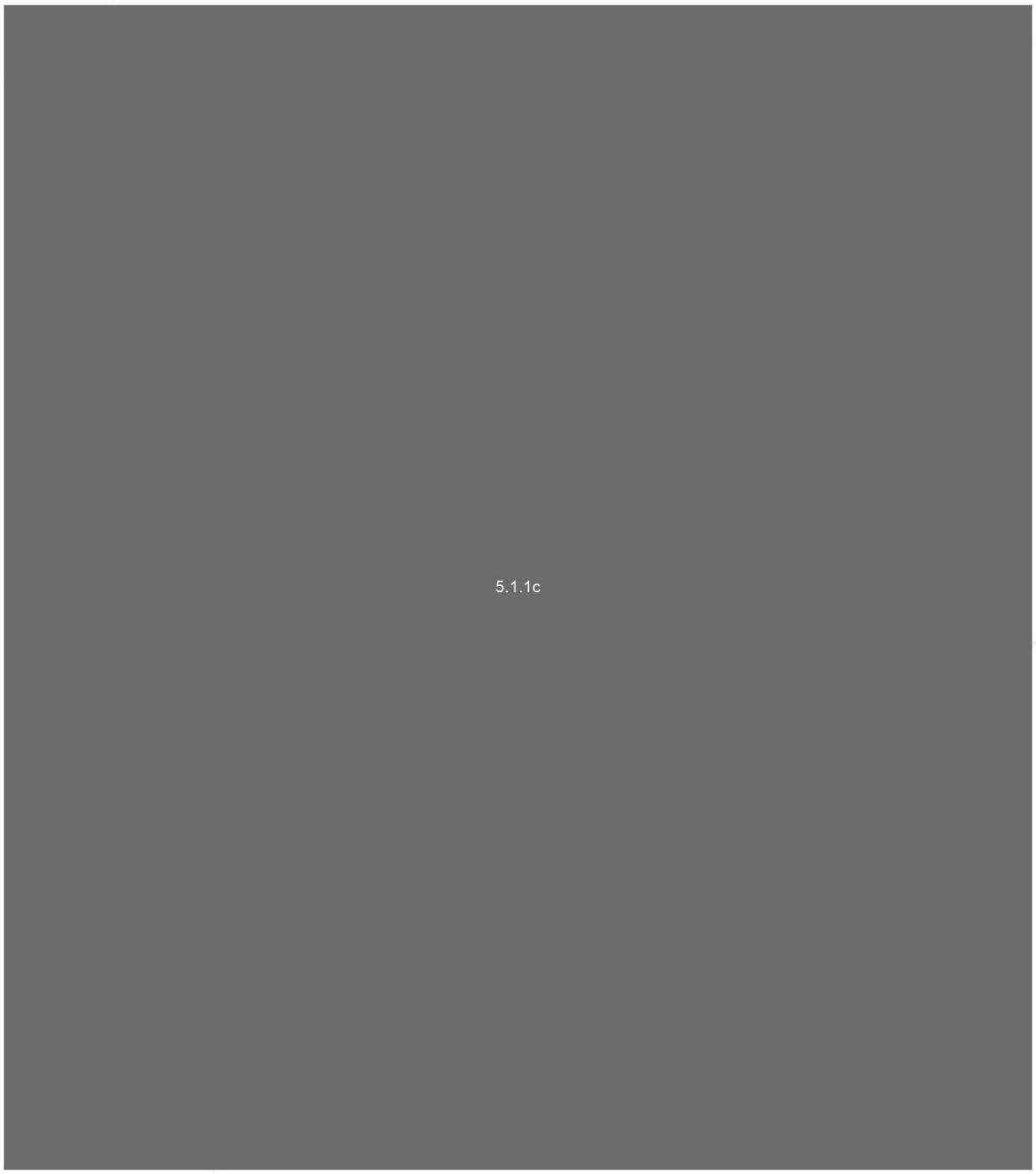

Syringes and safety needles contract number 5.1.1c 20

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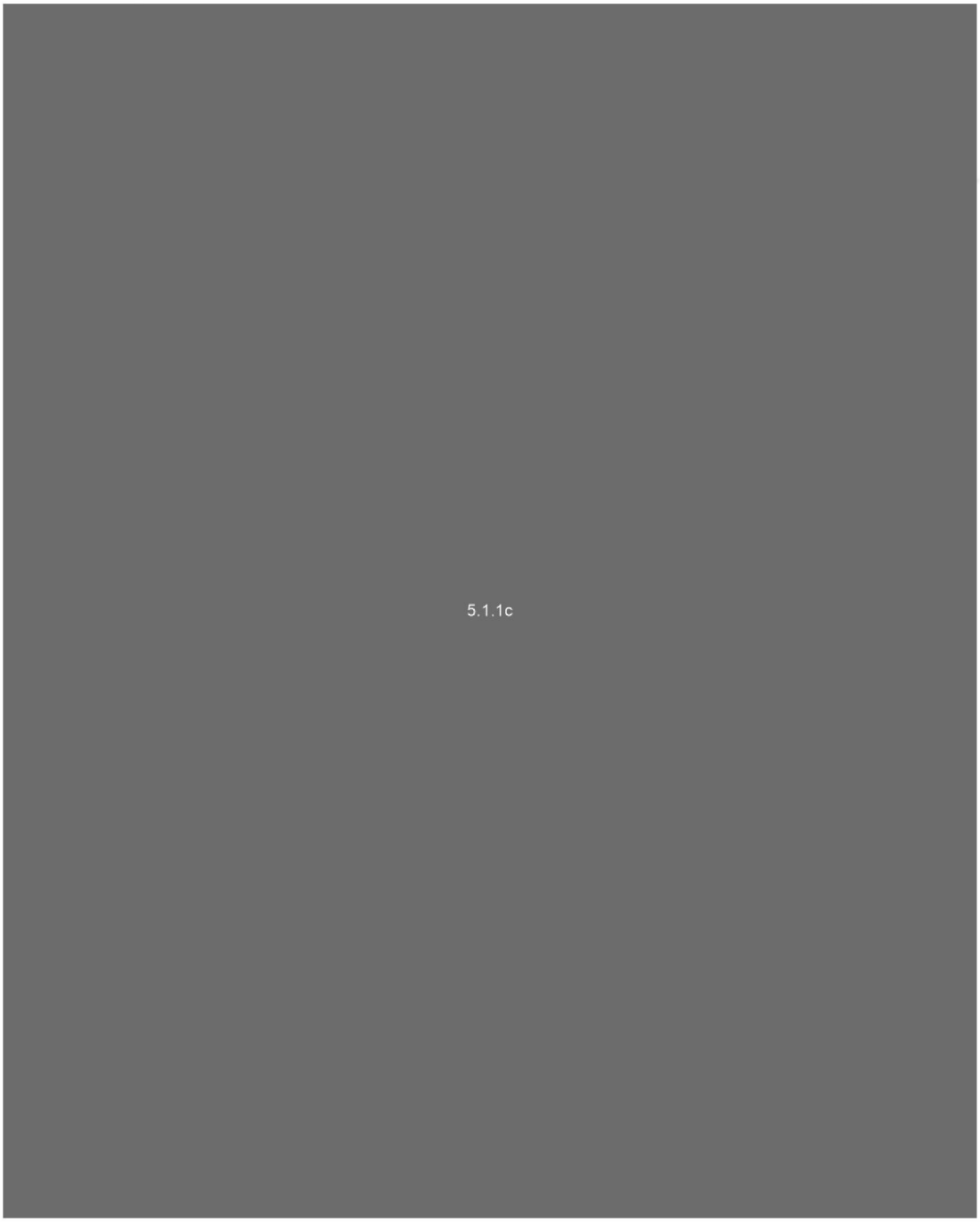
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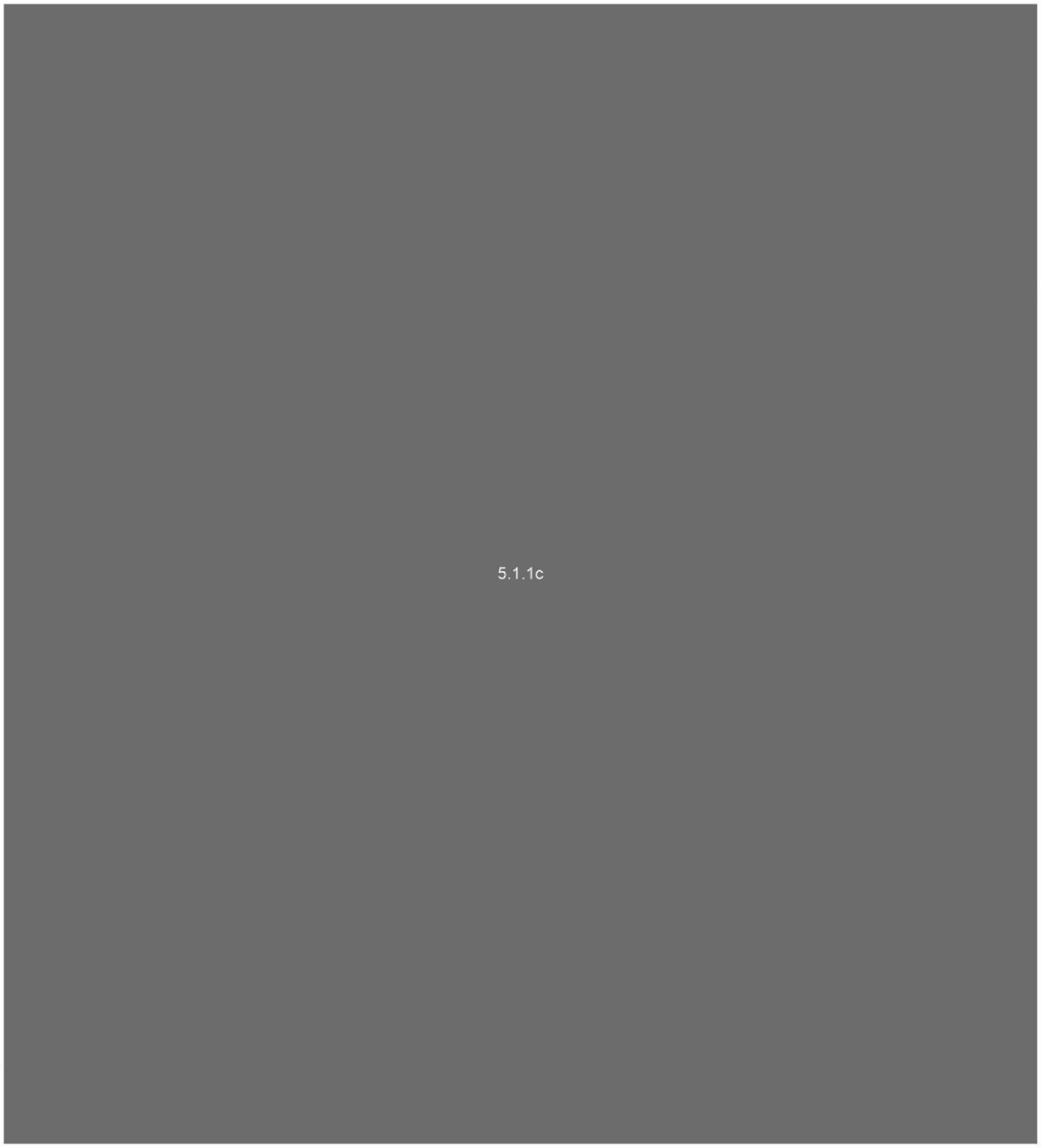
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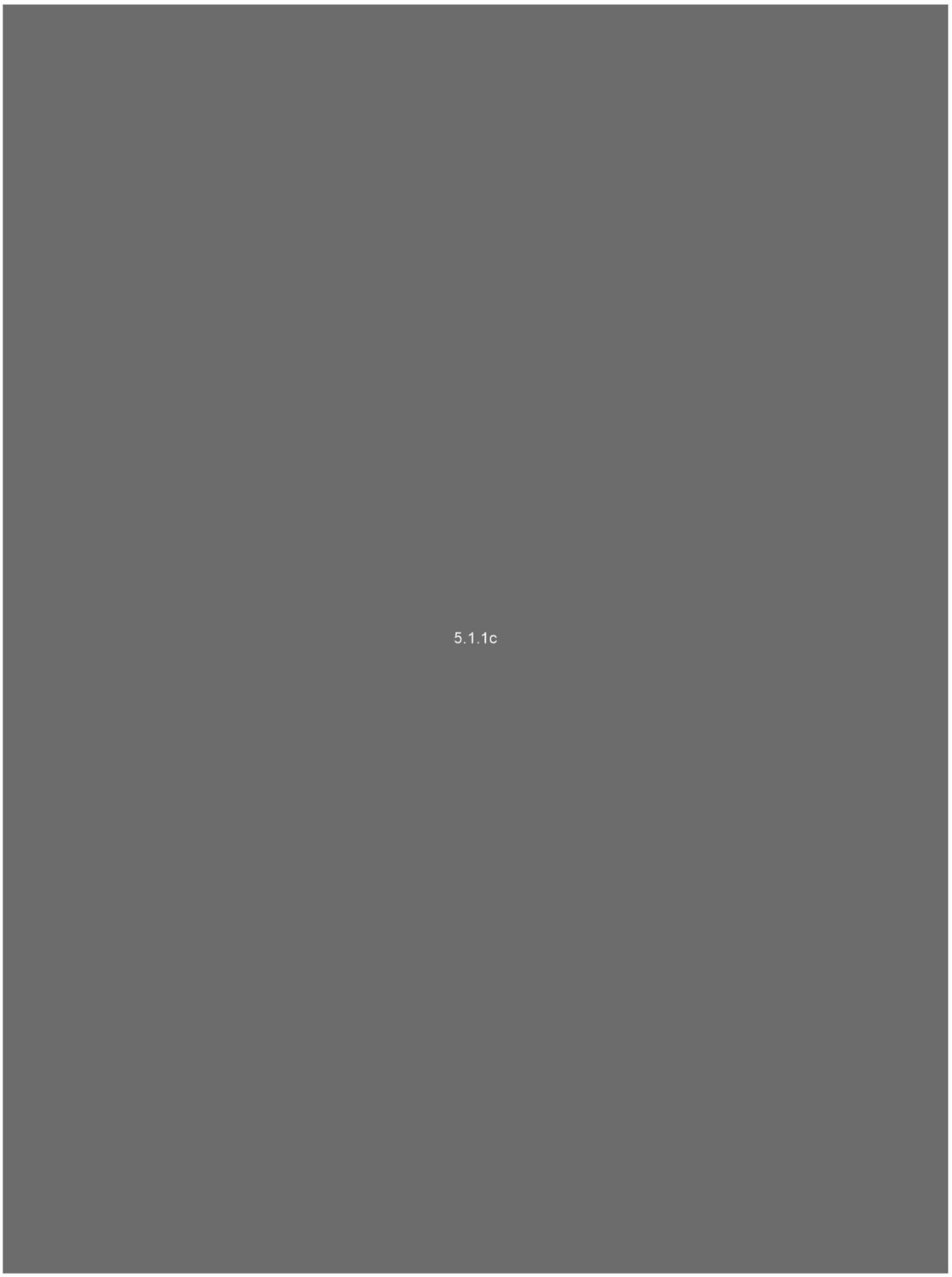
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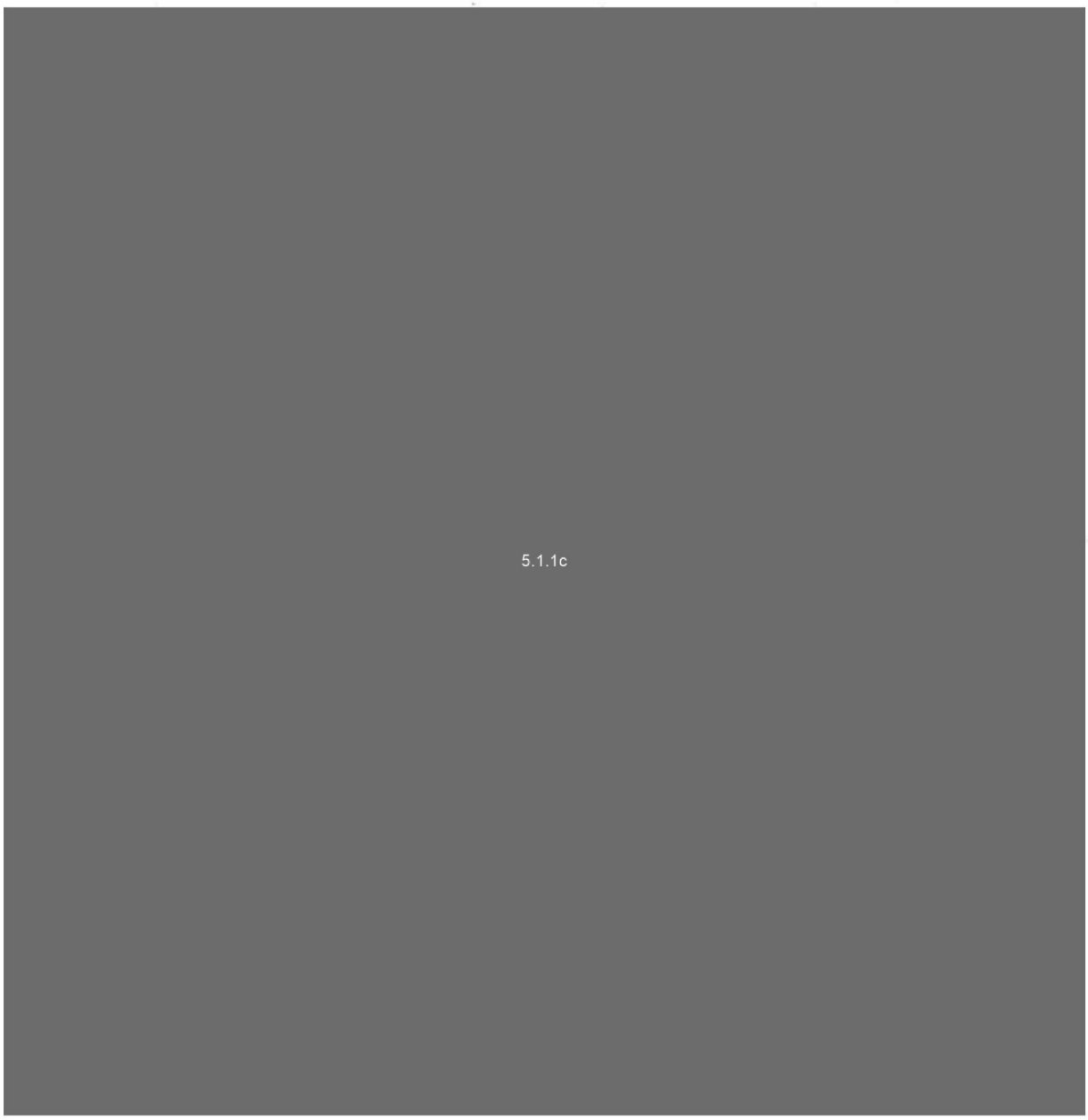
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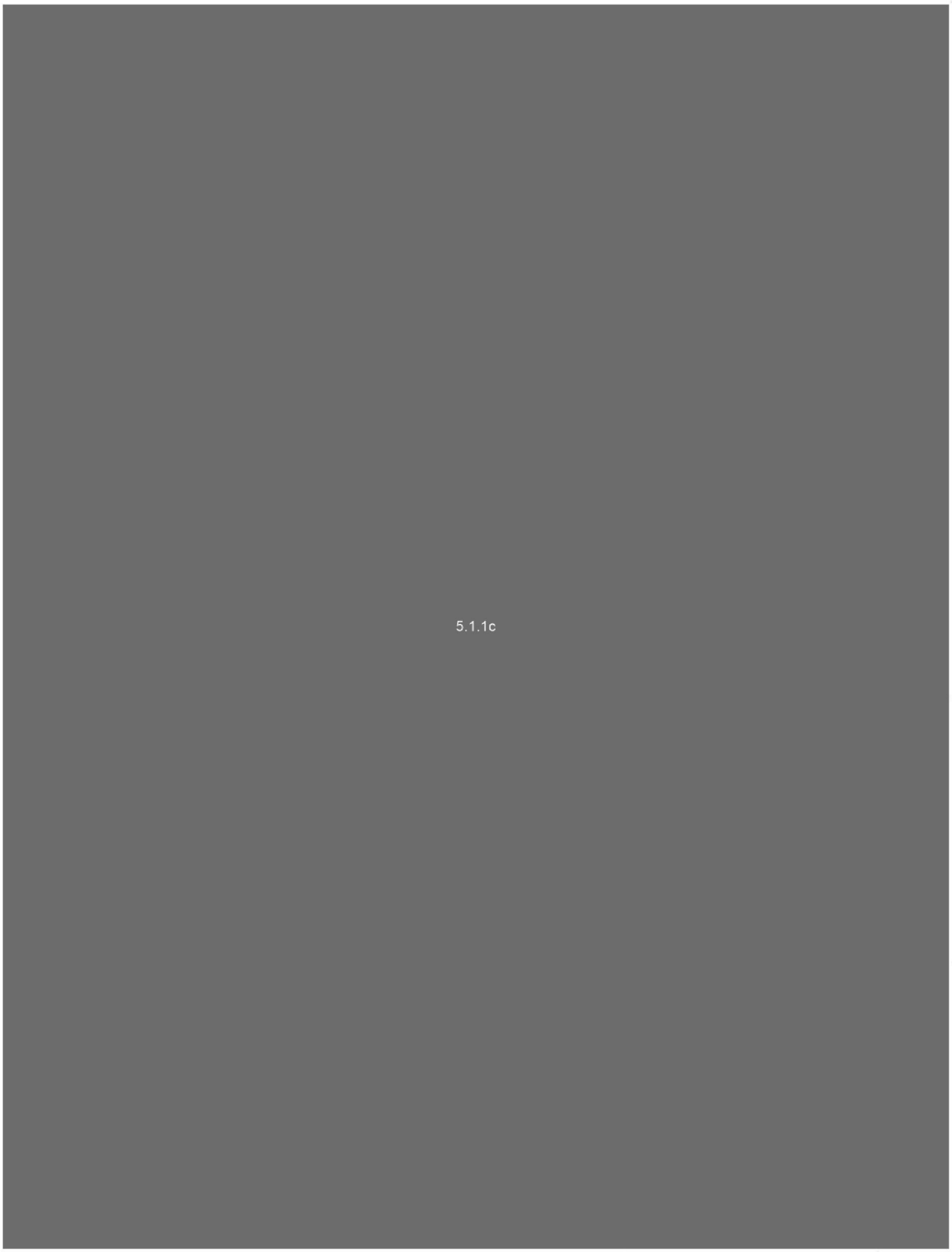
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Annex 1e. Delivery Schedule

5.1.2b	latest February 12th, 2021 – exact delivery date to be agreed between Parties latest April 30st, 2021 – exact delivery date to be agreed between Parties latest February 12th, 2021 – exact delivery date to be agreed between Parties latest April 30st, 2021 – exact delivery date to be agreed between Parties - latest February 12th, 2021 – exact delivery date to be agreed between Parties - latest April 30st, 2021 – exact delivery date to be agreed between Parties - latest February 12th, 2021 – exact delivery date to be agreed between Parties - latest April 30st, 2021 – exact delivery date to be agreed between Parties

Quality Technical Agreement

between

the State of The Netherlands

National Institute for Public Health and the Environment (RIVM)

and

MLS N.V.

concerning the supply of

Syringes and (safety) needles

SUMMARY OF AGREEMENTS AND RESPONSIBILITIES		RIVM	MLS
1.	**General**		
1.1	In case of any discrepancy between the Contract and the Quality Agreement, the latter shall prevail.	X	X
1.2	All contract documents shall be in the Dutch and/or English language. In case of any discrepancy between these two languages, the Dutch version(s) shall prevail.	X	X
1.3	Product is designed, produced, analysed and stored under MLS procedure current EU MDD 93/42/EEC.Starting as of May 26, 2021 the new Regulation 2017/745 and ISO 13485.	X	X
1.4	Supplier has a valid ISO 13485 certificate available. Supplier sends a copy of the certificate and any renewal of the certificate to the email address: 5.1.2e@rivm.nl.		X
1.5	The syringes and safety needles bear a CE mark.		X
2.	**Release of Product**		
2.1	The Legal manufacturer of the syringes and (safety) needles should have a person who is responsible for regulatory compliance.		X
2.2	Every individual delivery shall be accompanied by the following documentation as being part of the batch documentation: • a batch specific certificate of conformity (CoC) incl. item numbers of used primary and secondary packaging materials (labels, leaflets and packaging) if applicable. The certificate shall be signed by a quality responsible. The certificate shall state the function and title of the person. • a Certificate of Analysis (CoA) can be provided upon request for specific batch. The certificate shall be signed clearly by and stating the function and title of the responsible head of the laboratory who issued the certificate. Each certificate shall show at least the following information: product description, batch number, result of analysis, expiration date The supplier will send the batch specific documentation to email address: 5.1.2e@rivm.nl.		X
3.	**Packaging**		
3.1	The product must be delivered in its original packaging to prevent falsified medicinal products.		X
3.2	Every packaging shall contain 100 1ml syringes, 100 10ml syringes, 100 safety needles and 100 blunt fill needles, clearly marked with product name and batch number.		X
3.3	All labelling is in the Dutch or English language.		X
3.4	The transportation cartons are suitable for the chosen transport method. The packaging materials are suitable for air and terrestrial transport. The transportation cartons shall be clearly identified with name of manufacturer, product and batch number. All texts on the cartons shall be in the Dutch and/or English language and will be supported by the use of symbols.		X
4.	**Shipment**		
4.1	Supplier delivers procedure for packaging instructions and adventitious validation report for transport of the goods.		X
4.2	Importation from sites outside Europe shall be in accordance with regulatory and legal requirements.		X

4.3	Transport has to be executed using dedicated trucks if sent by road: transport of solely medical devices and/or pharmaceuticals, accommodated with despatching documentation of at least a CMR and packing list. It should be possible to link all documentation to each other		X
4.4	Packaging for shipment. All transportation cartons packed together on a Euro pallet are sealed in crimp foil (wrapping foil) and a dedicated tape/label from supplier has to be tampered to open.		X
4.5	Supplier sends a statement upon succesfull completion of transporation that there is no suspicion on falsification.	X	X
5.	**Deviations and complaint management**		
5.1	The supplier must have a comprehensively designed and correctly implemented Pharmaceutical Quality System according to ISO and current EU MDD 93/42/EEC. Starting as of May 26, 2021 the new Regulation 2017/745.		X
5.2	Any quality issue reported to and/or recorded by supplier that might eventually affect the quality and/or supply of the product, shall be reported to RIVM within 5 working days.	X	X
5.3	A system for the investigation and documentation of any quality issue is in place.		X
5.4	Supplier should provide documented proof that the shown quality issues were processed and completed according to ISO and current EU MDD 93/42/EEC. Starting as of May 26, 2021 the new Regulation 2017/745.		X
6.	**Change Control management**		
6.1	Supplier has a management system for follow-up, review, implementation and evaluation of changes.		X
6.2	Supplier is obliged to report all critical changes, proceeding to introduction, regarding all changes that may affect product quality or regulatory aspects.		X
6.3	Supplier is obliged to report all critical changes regarding the product information, shelf life, content or availability of the Goods to Purchaser immediately.		X
6.4	Supplier shall inform Purchaser as soon as possible and without any delay when there are changes (to be expected) regarding the applicable ISO 13485 certificate(s) and/or applicable CE marks.		X
7.	**Advisory notice and recall**		
7.1	Supplier will provide an advisory notice with supplementary information on use, modification, return or destruction of the product in any case needed.	X	X
7.2	Decision of product recall.	X	X
7.3	Notification to the Dutch Youth and Healthcare Inspectorate.	X	X
7.4	Organisation of recall.	X	X
As soon as possible 8.	**Documentation**		
8.1	Keeping of documentation related to release at the disposal of the competent authorities.		X
8.2	Keeping of reference samples related to release at the disposal of the competent authorities.		X
8.3	Keeping shipping documentation at the disposal of the competent authorities.	X	X
9.	**Assignment and subcontracts**		
9.1	Supplier shall not assign, in whole or in part, his obligations to perform under the Contract, except with RIVM's prior written consent.		X

9.2	Supplier shall notify RIVM in writing of all subcontracts awarded under the Contract if not already specified in his bid. Such notification, in his original bid or later, shall not relieve Supplier from any liability or obligation under the Contract or under the law.		X
10.	**Audits**		
10.1	Supplier agrees that RIVM or his duly authorised representatives have the right to inspect the production site(s), in correspondence with ISO 13485, MDD 93/42/EEC and starting as of May 26, 2021 the new EU Regulation 2017/745, before contract undersigning and at any time during the course of the contract.	X	X
10.2	Supplier agrees that RIVM or his duly authorised representatives have the right to audit the premises where the products are stored in correspondence with ISO 13485 and Current MDD 93/42/EEC and starting as of May 26, 2021 EU Regulation 2017/745, before contract undersigning and at any time during the course of the contract.	X	X
10.3	Corrective and preventive actions resulting from the observations during the audit have to be performed in the soonest possible way and reports may be evaluated and inspected by RIVM.	X	X

[redacted]

5.1.2e

5.1.2e

Date:

Date: 6-10-20

Annex 3: Certificate of Payment

Rijksinstituut voor Volksgezondheid en Milieu
Ministerie van Volksgezondheid, Welzijn en Sport

CERTIFICATE OF PAYMENT

Concerning the supply of (Brand Name Vaccine)	
Batch Number	
Supplier	
SAP Article Number RIVM	
PO Number RIVM	
Number of Doses	
Number of Packages	

Acting on behalf of RIVM, the (first) undersigned, authorised for this purpose by the RIVM, hereby declares that the vaccines and necessary documents have been supplied to RIVM timely, according requirements and thereby deemed to have been accepted

Bilthoven, Date

On behalf of the RIVM,

Name ☐ 5.1.2e ☐ 5.1.2e

Position ☐ Qualified Person ☐ Responsible Person

Signature

This Certificate of Payment relieves only payment of the received invoice of the above mentioned batch

Annex 4 Communication table

Purchaser		Supplier	
Function	**Contract management/ Purchaser**	**Function**	**Customer service Benelux**
Name	5.1.2e	Name	5.1.2e
e-mail	5.1.2e @rivm.nl	e-mail	5.1.2e @mls.be
telephone	+31 (0) 5.1.2e	Telephone	+32 (0) 5.1.2e
Function	**Logistics**		
e-mail	5.1.2e @rivm.nl		
Finance	5.1.2e @rivm.nl +31 (0)30 274 2525	Finance e-mail Telephone	5.1.2e 5.1.2e @mls.be +32 (0 5.1.2e
Function	**Qualified/Responsible Person**	Function	5.1.2e 5.1.2e
e-mail	5.1.2e @rivm.nl	e-mail	5.1.2e @mls.be
telephone	+31 (0 5.1.2e	Telephone	+32 (5.1.2e
Function	5.1.2e	Function	5.1.2e
Name	5.1.2e	Name	5.1.2e
e-mail	5.1.2e @rivm.nl	e-mail	5.1.2e @mls.be
telephone	+31 (0 5.1.2e	Telephone	+32 (5.1.2e