Contract

between

the State of the Netherlands

National Institute for Public Health and the Environment (RIVM)

and

Becton, Dickinson B.V.

concerning the supply of

Syringes and (safety) needles

contract number 5.1.1c

Content

Annexes

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

Becton, Dickinson B.V., having his office at Lange Dreef 11, 4131NJ Vianen, The Netherlands, duly represented by 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:

5.1.2e

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 and 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

5.1.2e

to be delivered in at most 4 deliveries, as specified in Annex 1. For the optional needles a delivery time of two months after placing the purchase order is applicable.
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 150 cm).
The syringes and safety needles have a CE-mark and must comply with the essential requirements of the MDD 93/42/EEC or the new Regulation 2017/745 effective date May 26, 2021. Manufacturers must have a quality management system that complies with the standard ISO 13485 or the new Regulation 2017/745 effective date May 26, 2021.
The syringes and safety needles shall have a remaining shelf life after delivery to the RIVM of at least 48 months.
For the ordering and the supply of the 5.1.1c no cancellation of order will be accepted by Supplier.

The syringes and safety needles have a CE-mark and must comply with the essential requirements of the MDD 93/42/EEC or the new Regulation 2017/745 effective date May 26, 2021. Manufacturers must have a quality management system that complies with the standard ISO 13485 or the new Regulation 2017/745 effective date May 26, 2021.
The syringes and safety needles shall have a remaining shelf life after delivery to the RIVM of at least 48 months.
For the ordering and the supply of the 5.1.1c no cancellation of order will be accepted by Supplier.
However cancellation of 5.1.2b of the ordering and supply of the total volume of 5.1.1c 5.1.1c and the BD™ Blunt Fill needles will be accepted by Supplier if cancellation will take place 4 months before the planned delivery date.
In case no BD Eclipse™ safety needles are available in the period January – August 2021, and needles are needed by Purchaser, BD will guarantee as back up the supply of BD Microlance™ needles (volumes corresponding to supplied syringes).

2.2 This Agreement is entered into by Supplier for the benefit of Supplier, and any Affiliate of the Supplier.

3. Delivery

3.1 The delivery of the goods shall be Ex Works from the warehouse of Supplier.

3.2 Supplier shall deliver at least 5.1.1c 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 € 100,000 (one hundred thousand euros) and the amount of the total liability will be capped at € 1,000,000 (one million euros). 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 at least 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 6.3 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 *of the Contract Price of the recalled Goods. 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.

5.1.2e

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 an Ex Works basis (Becton Dickinson Distribution Center N.V., Temse, Belgium) to the warehouse in The Netherlands, of which the location will be specified by RIVM when placing the purchase order(s).

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

within a period of maximum 2 weeks 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 12.1, 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 2.2 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 2.2 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
Annex 1c
Annex 1d
Annex 1e Delivery Schedule
Annex 2 Quality Technical Agreement
Annex 3 Certificate of Payment
Annex 4 Communication table

5.1.1c

15. Term and termination

15.1 This Contract will enter into force on September 1, 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.

Signatures

5.1.2e

h,

For **Becton, Dickinson B.V.**

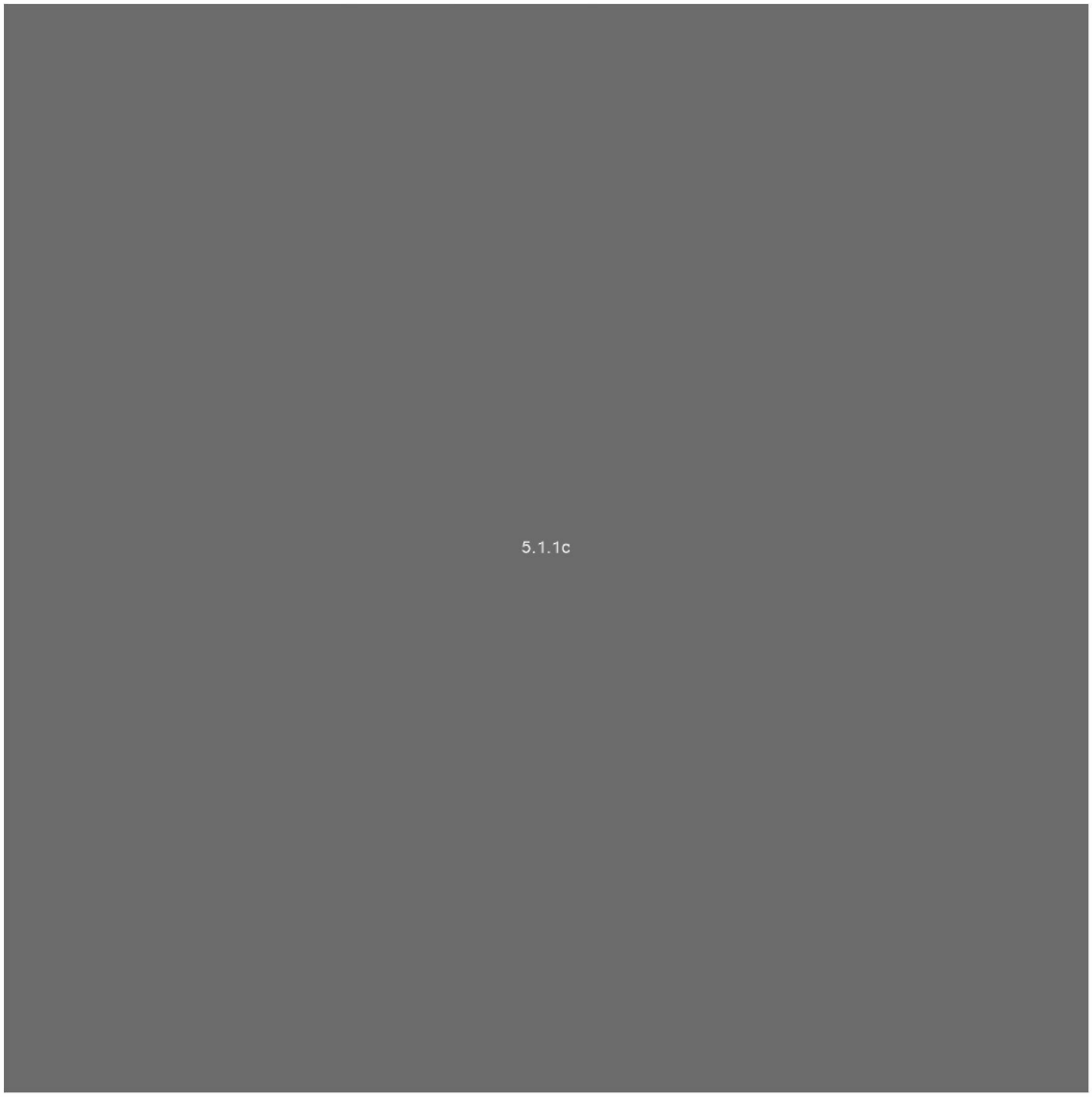
5.1.2e

(authorised signature)

Name : 5.1.2e
Position : 5.1.2e

Place : Bilthoven
Date : 06-Aug-2020

Place : Erembodegem
Date : 12/08/2020

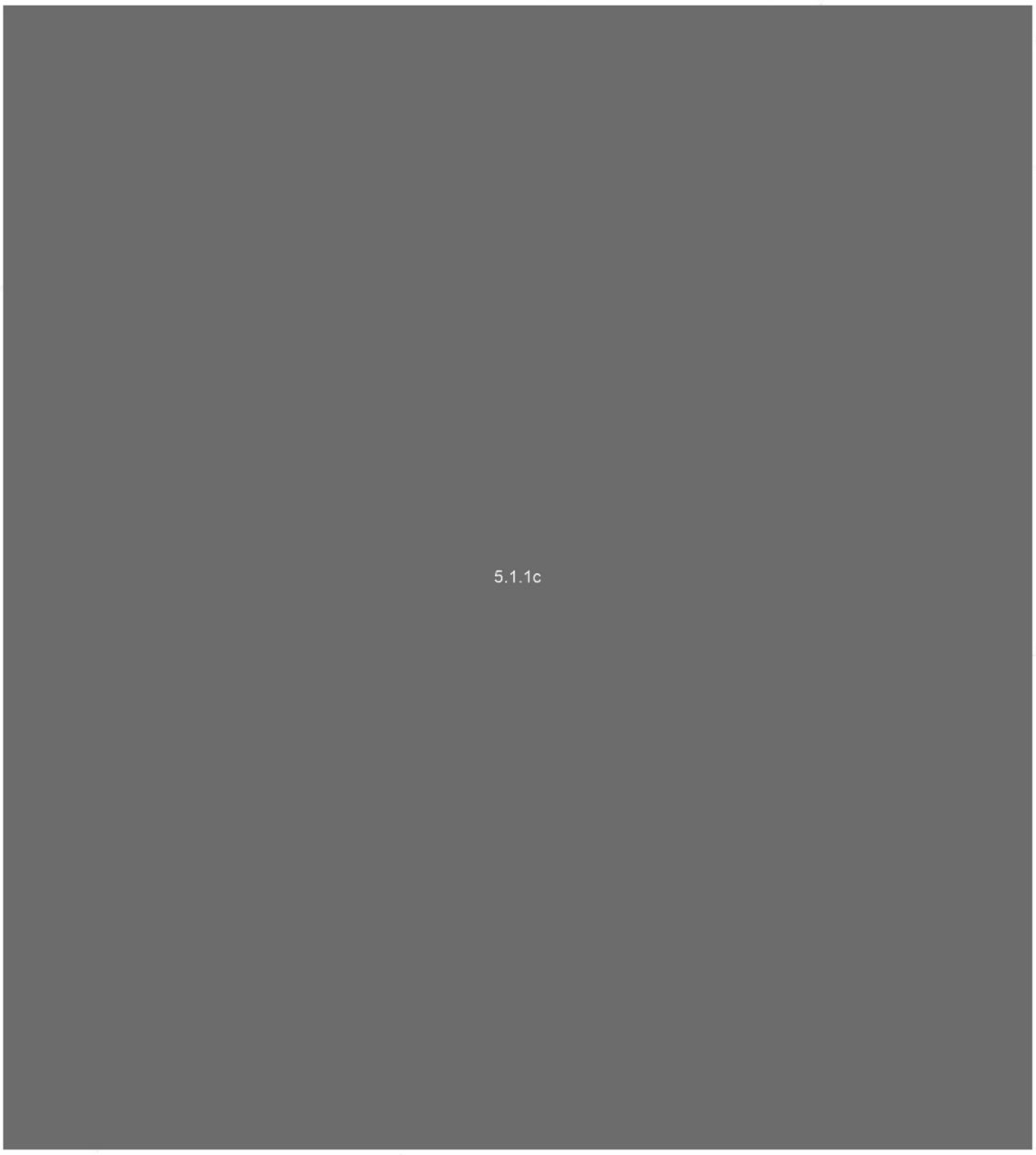


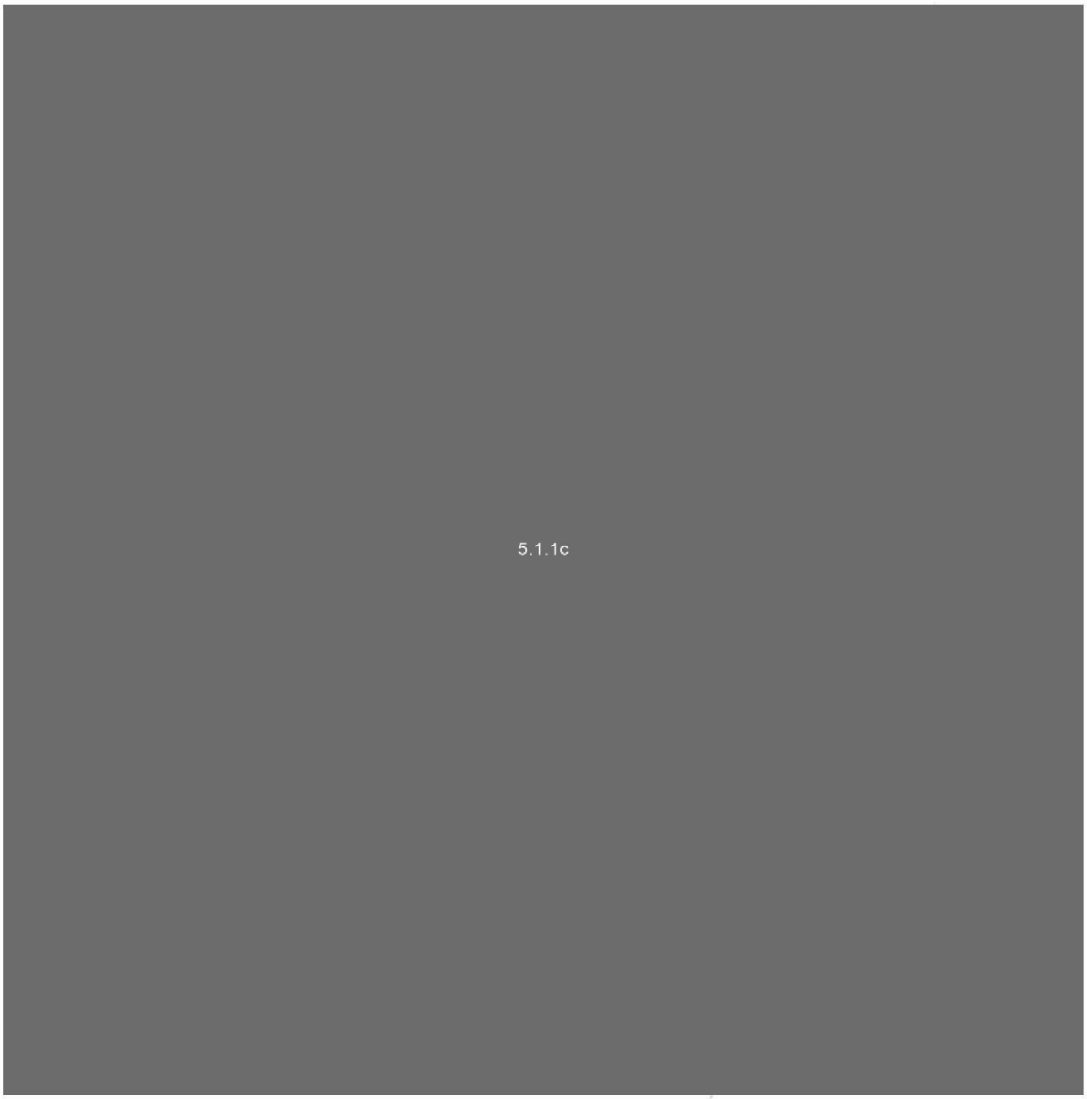
The transport and storage conditions for all above products :
Store in a dry and warm place, not exposed to strong light

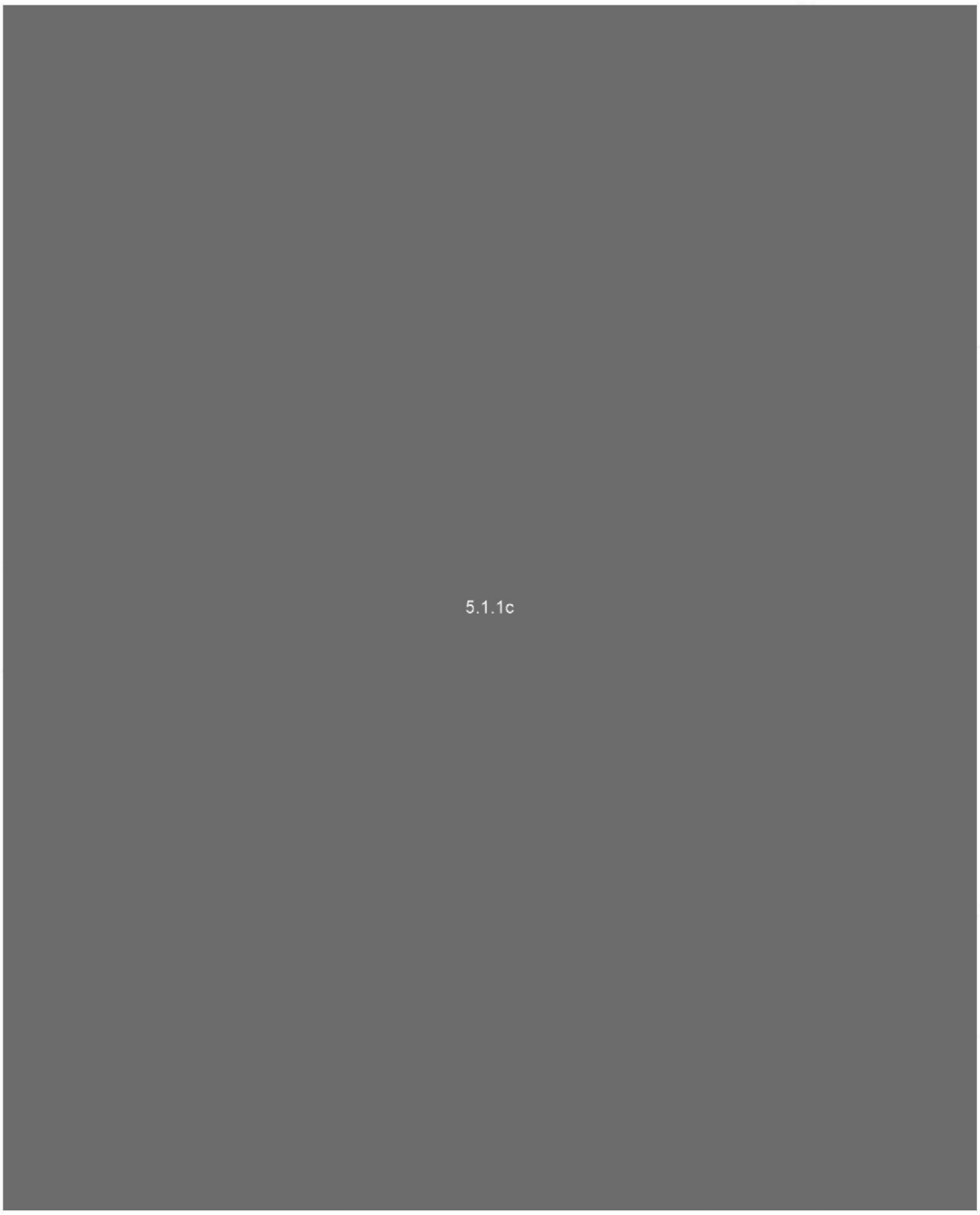
Documents:

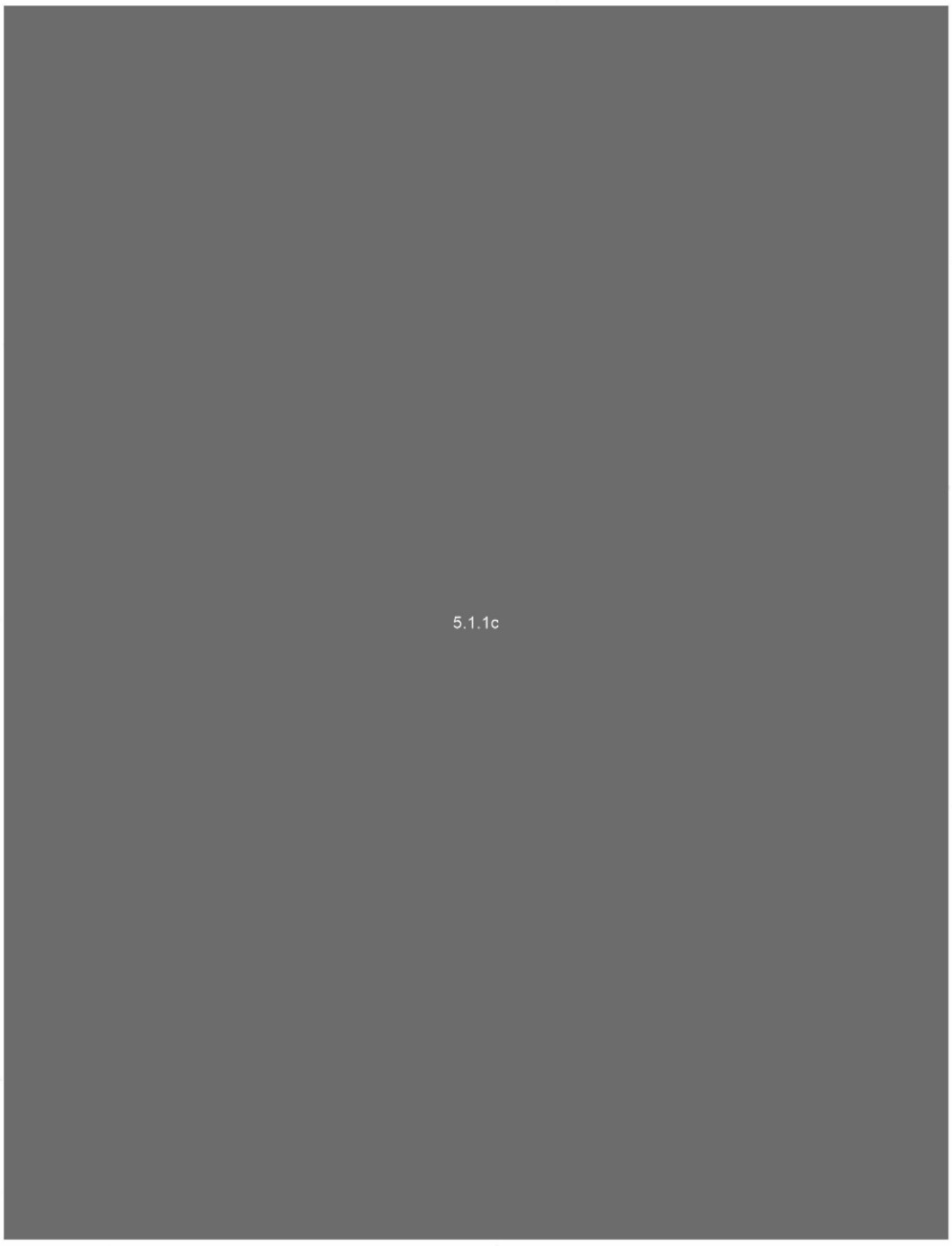
Batch certificate	available
Certificate of Conformity per batch	available
Certificate of Transport Release (CoTR)	N/A (ex-works)

5.1.2e








5.1.1c

Harmonized Standards	
EN ISO 22442-1:2007	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
EN ISO 22442-2:2007	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
Non-Harmonized Standards	
EN ISO 7864:1993	Sterile hypodermic needles for single use
EN ISO 6009:1992/COR 1 2008	Hypodermic needles for single use – Colour coding for identification
ISO 9626	Stainless steel tubing for the manufacture of medical devices
ISO 23908:2011	Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Note:
The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.11 Classification

Class IIa Medical Devices as per Annex IX, Section III, Rule 6 of the Medical Device Directive 93\42\EEC.
Rule 6 reads, "All surgically invasive devices intended for transient use are in Class IIa". Hypodermic Needles are intended for transient use, i.e., continuous use for less than 60 minutes as per Annex IX, Section I, paragraph 1.1 and are surgically invasive as per Annex IX, Section I, paragraph 1.2. Paragraph 1.2 indicates that for the purposes of the directive, devices other than those which produce penetration through a non-established body orifice, shall be treated as surgically invasive devices.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Eclipse™ SmartSlip™ is referenced as follows:
GMDN Code: 59230
GMDN Term: Hypodermic Needle, Single Use, Sterile

1.13 Good Manufacturing practices

The entire manufacturing and testing processes are following the Good Manufacturing Practices as specified below:

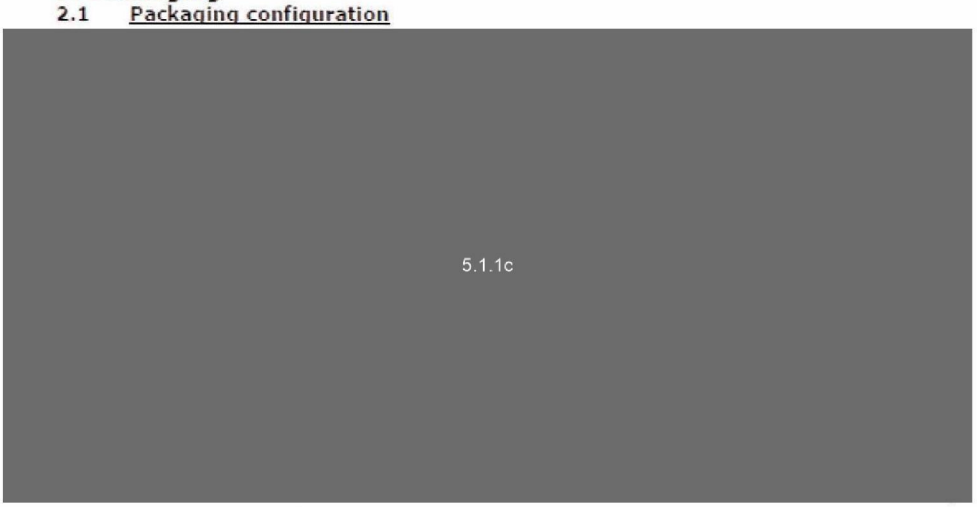
- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures.
- BD operates a system of internal and external audits to maintain compliance.
- BD confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact (*Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food)* is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.

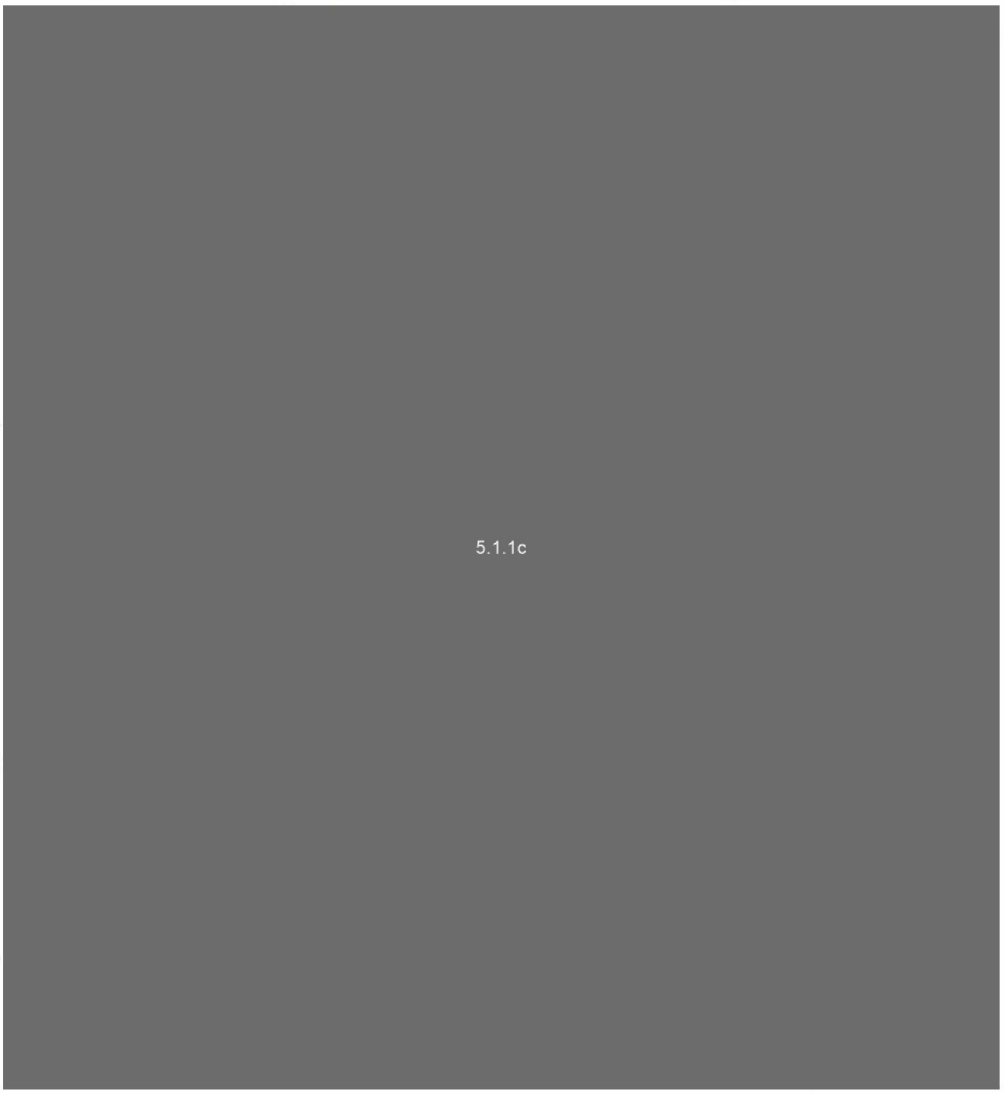
2. Packaging

2.1 Packaging configuration



2.2 Packaging material

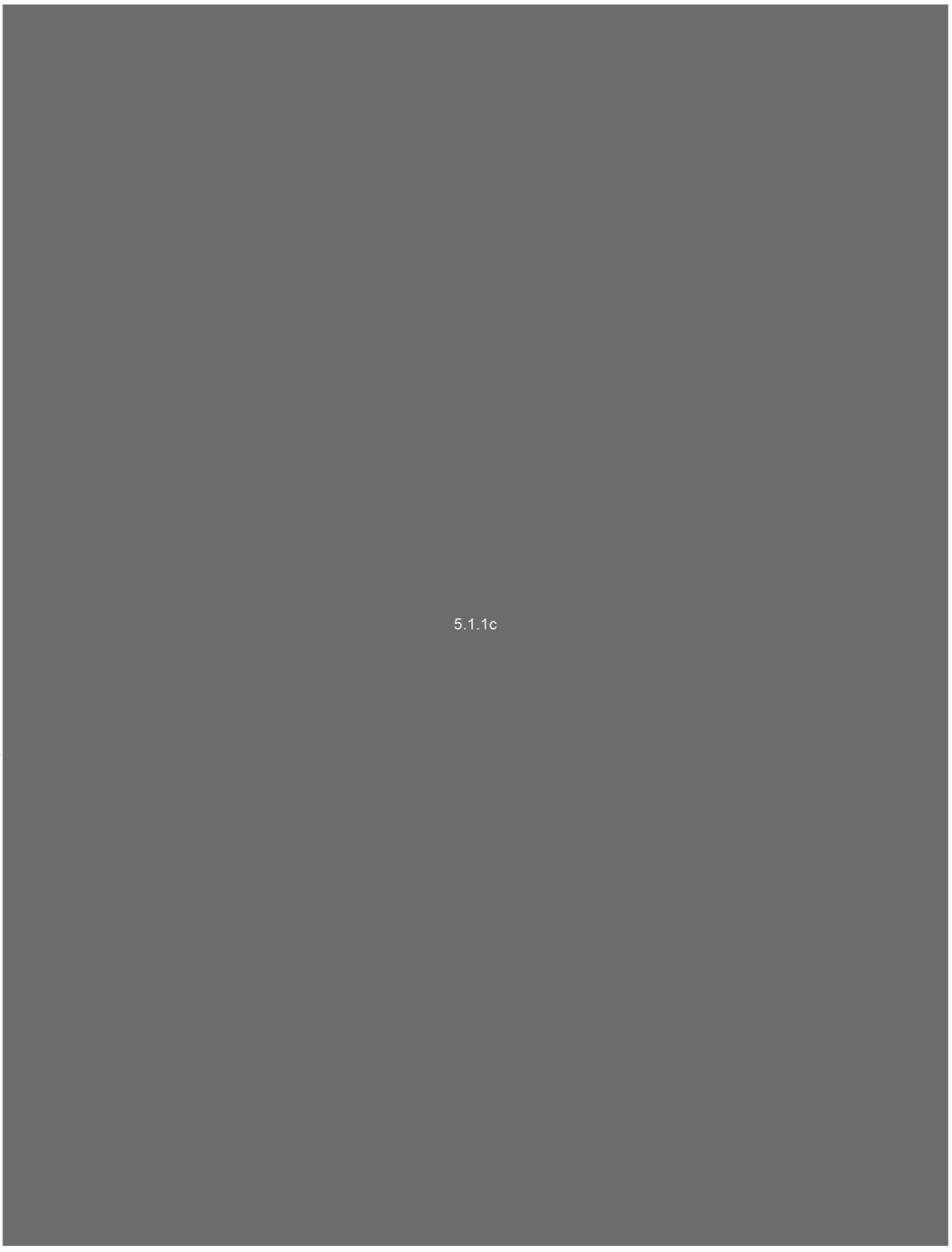
Component	Material
Top Web	Film
Blister Bottom Web	Thermoformable Plastic
Shelf Carton	Corrugated Carton
Shipping Case	Corrugated Carton



5.1.1c

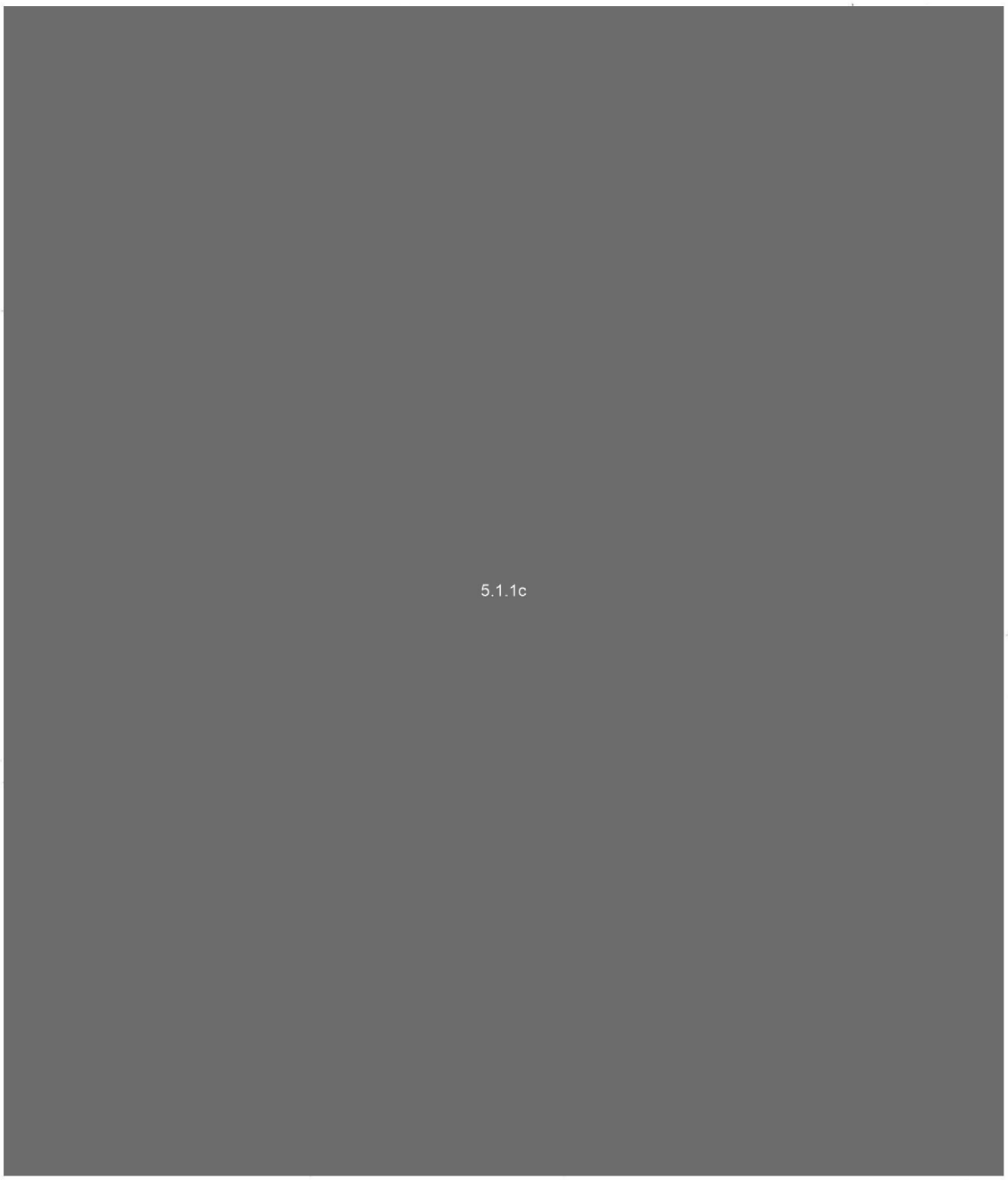
5.1.2e

REVISION	CHANGE SUMMARY
01	Initial release according to new template



Syringes and safety needles contract number 5.1.1c 22

5.1.2e



Syringes and safety needles contract number	5.1.1c	23	5.1.2e

5.1.1c

Syringes and safety needles contract number 5.1.1c 24

5.1.2e

1.4 Materials

5.1.1c

Syringes and safety needles contract number 5.1.1c 25

5.1.2e

5.1.1c

Syringes and safety needles contract number 5.1.1c

5.1.2e

1.10 Standards

As per extract from the Declaration of Conformity linked to CE Certificate number 95 06 0006 CP:

Harmonized Standards	
EN 556-1:2001 /AC:2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993 series	Biological evaluation of medical devices
EN ISO 11135-1:2007	Sterilization of health care products. Ethylene oxide. Part 1:Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-2:2009	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1: 2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006 /AC:2009	Sterilization of medical devices – Microbial methods- Part 1 : Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
EN ISO 13485:2016/ AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices. Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.
EN 20594-1: 1993/ A1:1997 / AC:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.
Non-Harmonized Standards	
EN ISO 7886-1:1997	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 7864:2016	Sterile hypodermic needles for single use
EN ISO 6009:2016	Hypodermic needles for single use. Colour coding for identification
EN ISO 9626:1995/ A1:2001	Stainless steel needle tubing for the manufacture of medical devices

Note:

The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.11 Classification

- BD Emerald™ with sterile needle, SKU 307729, 307730, 303119, 303124, 307728, 307740, 307741, 302909, 303032, 303034, 303044, 303047, 303109, 303112, 303113, 307742, 307743, 307734, 307732, 307733, 307735, 302910, 303048, 303049, 303111, 303114, 303115, 307739, 307737 and 307738 are classified as Medical Devices class IIa sterile with a measuring function classification rule 6 according to Medical Devices Directive 93/42/EEC.

- BD Emerald™ with Blunt fill needle, SKU 303221, 303139 and 303140 are classified as Medical Devices class I sterile with a measuring function, classification rule 2 according to Medical Devices Directive 93/42/EEC.
- BD Emerald™ without needle, SKU 307727, 302986, 307731, 307736 and 303219 are classified as Medical Devices class I sterile with a measuring function, classification rule 2 according to Medical Devices Directive 93/42/EEC.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Emerald™ are referenced as follows:
GMDN Code: 47017
GMDN Term: General purpose syringes

1.13 Good Manufacturing practices

The entire manufacturing and testing processes are following the Good Manufacturing Practices as specified below:

- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures.
- BD operates a system of internal and external audits to maintain compliance.
- BD confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.14 Other information

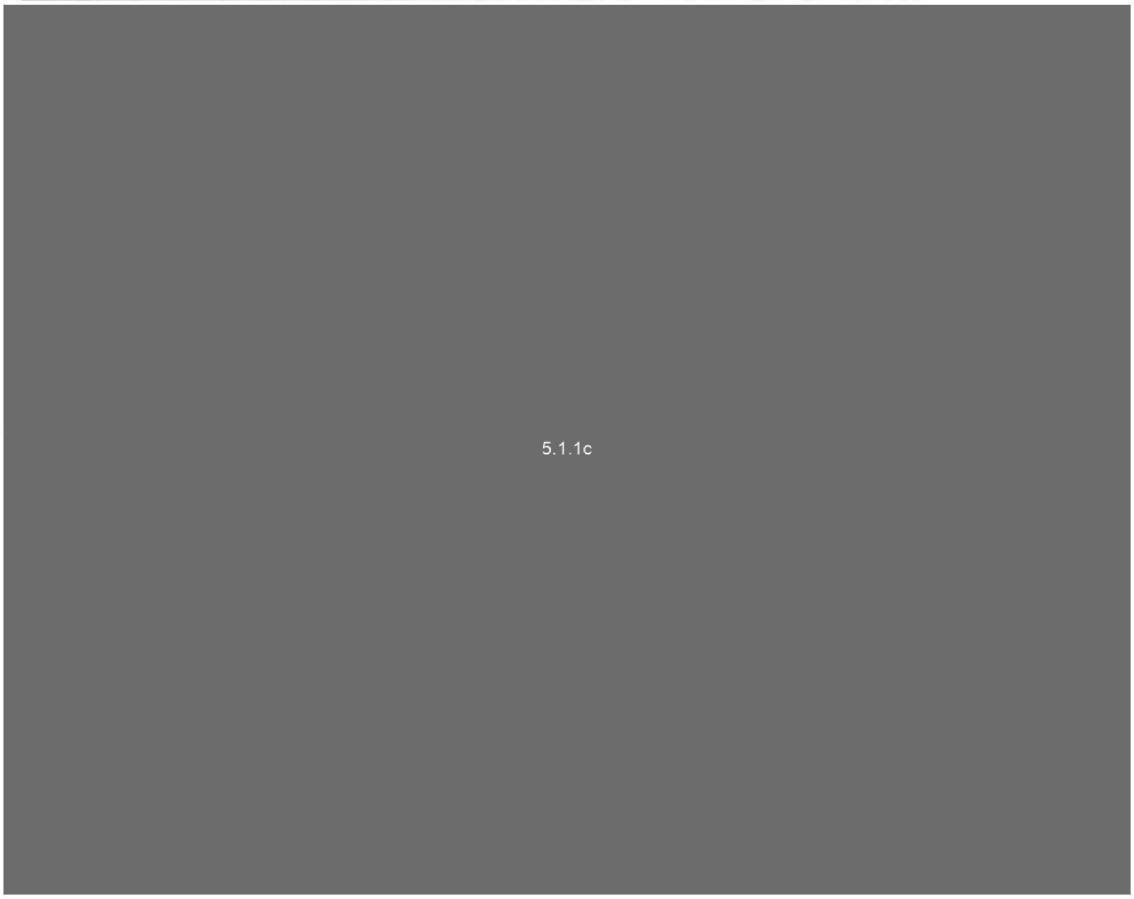
- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact (*Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food)* is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.

2. Packaging

2.1 Packaging configuration

5.1.1c

Syringes and safety needles contract number 5.1.1c 29 5.1.2e

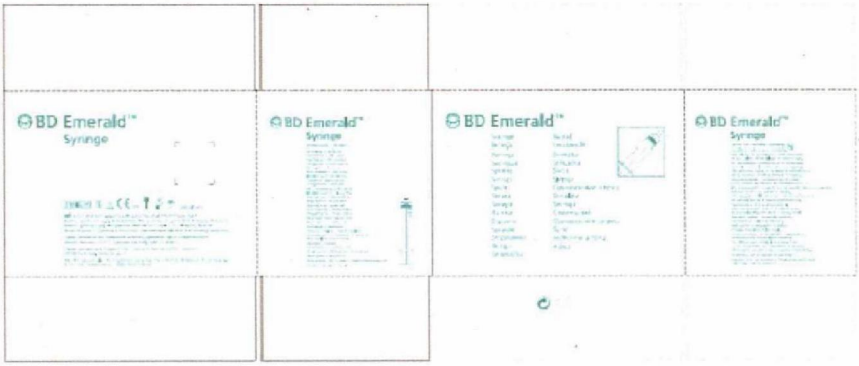


Syringes and safety needles contract number 5.1.1c 30

Shelf Box carton extracted from document DGF376 related to reference 307729:

Shelf Box label extracted from document DGL1770 related to reference 307729:

Shipping Case carton extracted from document DGC185 related to reference 307729:



Shipping Case Label extracted from document DGL1785 related to reference 307729:

REVISION	CHANGE SUMMARY
01	Initial release according to new template

Annex 1c. 5.1.1c

Form

Document Number: *V200QARA-SWI-01-A* Revision Level: 01

TITLE: Technical Data Sheet 10 Page 1 of

5.1.1c

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

TDS number: V201-013 – Rev. 01
2019-June

1. General Information

1.1 Intended use

The BD Fill and Filter Needles are used for aspiration of fluids from vials and ampoules. The BD Fill and Filter Needles are not for skin injections.

1.2 General description

The BD Filter and Fill Needles are single use medical devices, sold to healthcare professionals, used for aspiration of fluids from vials and ampoules and are not for skin injections.
The BD™ Blunt Fill Needles have female luer fittings, which mate to male luer fittings.

5.1.1c

Note: Please check BD catalog number availability in your country.
The BD Product Description can slightly differ from the DoC, please always use the BD Catalog Number.

Further features: N/A

1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
305211 305180 305181 305183	**Address:** Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 United States **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificate No.: 252.308	**Address:** BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States **ISO 13485** Certificate No.: MD19.2143	Becton Dickinson Distribution Center NV Laagstraat 57 B-9140 Temse Belgium
303129	**Address:** Becton Dickinson S.A. Ctra. De Mequinenza. s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	CE certified with AEMPS (0318) Certificate No.: 2015 03 0838 CP	**Address:** Becton Dickinson S.A. Ctra. De Mequinenza. s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN **Address:** BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States **ISO 13485** Certificate No.: MD19.2143	N/A

1.4 Materials

Component	Material
5.1.1c	

1.5 Materials of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

Material	Comment
[redacted]	[redacted]

5.1.1c

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per April 2019, BD has not identified any chemicals in the articles and packaging of BD Blunt Fill and Filter Needles, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on June 2018 according to Art. 59 (1,10) of the Regulation (EC) N° 1907/2006 (REACH).

1.7 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

1.8 Sterilization method

5.1.1c

1.9 Shelf life and storage conditions

The BD Blunt Fill and filter Needles shelf life have been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Blunt Fill and filter Needles reference 305211, 305180, 305181, 305183 and 303129 have a shelf life of 5 years.

Store in a dry and warm place, not exposed to strong light.

1.10 Standards

As per extract from the Declaration of Conformity document number DOC DTF0006 linked to CE certificate number 252.308:

Harmonized Standards	
EN 556-1:2001/ AC:2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Harmonized Standards	
EN ISO 11137-2:2013	Sterilization of health care products – Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN 20594-1:1994	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.
EN 1707:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings
EN ISO 22442-1:2007	Medical devices utilizing animal tissues and their derivatives -- Part 1: Application of risk management
EN ISO 22442-2:2007	Medical devices utilizing animal tissues and their derivatives -- Part 2: Controls on sourcing, collection and handling
EN ISO 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
Non-Harmonized Standards	
EN ISO 9626:1991/ A1:2001	Stainless steel needle tubing for the manufacture of medical devices

Note:
The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the DoC.

1.11 Classification

BD™ Fill and Filter Needles (305211, 305180, 305181 and 305183) are Class I Medical Devices, sterile, as per Annex IX, Section III, Rule 1 of the Medical Device Directive 93/42/EEC.

BD™ Blunt Fill Needle (303129) is class I, sterile medical device as defined in the Medical Devices Directive (93/42/EEC) Annex IX, Section III rule 2.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Blunt Fill and Filter are referenced as follows:

5.1.1c

1.13 Good Manufacturing practices

The entire manufacturing and testing processes are following the Good Manufacturing Practices as specified below:

- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures.
- BD operates a system of internal and external audits to maintain compliance.
- BD confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact (*Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food)* is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- There is no separate Instruction for Use, IFU, relevant information is captured on the shelf box graphics.

2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
305211					
305180					
305181		5.1.1c			
305183					
303129					

*"No": IFU may be available but not as an insert.

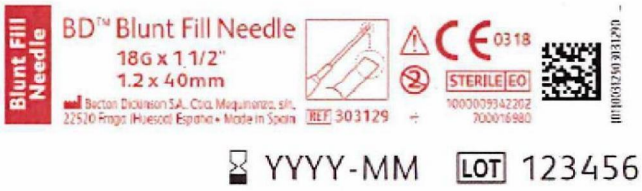
2.2 Packaging material

Component	Material
Unit Pack	**For references 305211, 305180, 305181 and 305183:** Top web: Paper Bottom web: Thermoformable plastic **For reference 303129:** Top Web – Polyamide/Polyethylene Bottom Web – Paper
Shelf Box	Corrugated carton
Shipping Case	Corrugated carton

2.3 Examples of labeling

Labels: According to European Medical Device directive, labels are multilingual.

Primary Packaging Label (Top Web) extracted from document 1000093422 related to reference 303129:

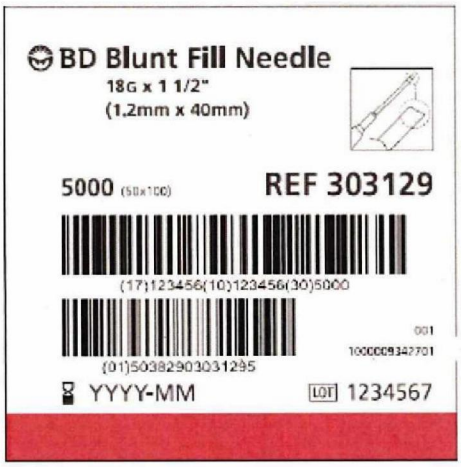


Shelf Box extracted from document 10000093423 related to reference 303129:

Shelf Box label extracted from document 10000093426 related to reference 303129:

Shipping Case extracted from document 1000093424 related to reference 303129:

Case Label extracted from document 10000093427 related to reference 303129:



REVISION	CHANGE SUMMARY
01	Initial release according to new template

Annex 1d. TDS File BD Microlance™ Needle

5.1.1c

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com
TDS number: V201-007 – Rev.03
2020-June

1. General Information

1.1 Intended use

BD Microlance™ 3 hypodermic needles are a single-use medical device intended for injection and/or aspiration of medical fluids, understood as both bodily fluids (blood, etc.) and medicines. The needles are also supplied non-sterile in bulk. This product is sold to other device manufacturers and is packed in bulk and labelled "non-sterile".

1.2 General description

BD Microlance™ 3 hypodermic needles are manufactured in different sizes, depending on the various exterior diameters and lengths of the cannulas. Each type of needle is recognized by the colour of the hub and by the identification system, both by the International System of Units (measurement in millimetres) and the American system (measurements in inches).

BD conventional needle design, materials and clinical application are based on well-established technologies and procedures. Sterile, single use disposable Microlance needles have been manufactured by BD and used successfully for over 50 years. The needle hub has a female luer fitting which mates to male luer fittings and is compatible with luer slip or luer lock syringes.

The range of products is as follows:

5.1.1c

Note: Please check BD catalog number availability in your country.
The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to the BD Catalog Number.

Further features: N/A

1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
300094* 300300* 300400* 300600* 300635* 300637* 301155* 301500* 301700* 301750* 301900* 302200* 303800* 304000* 304100* 304300* 304622* 304827 301300 304434 301156 304432 304727 300900 301000 300800 300700	**Address:** Becton Dickinson S.A. Carretera de Mequinenza, s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	CE certified with AEMPS (0318) Certificate No.: 95 06 0006 CP	**Address:** Becton Dickinson S.A. Carretera de Mequinenza, s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	N/A

* Ongoing project: BD is transferring the legal manufacturer from BD Drogheda (Ireland) to BD Fraga (Spain) and from Notified Body NSAI (Ireland) to AEMPS (Spain), completion date in 2020.

There will be no renewal of CE certificate 252.157 (NSAI 0050) from Drogheda as products are currently transitioning to the CE certificate number 95 06 0006 CP (AEMPS 0318) (as per above table). There is no change to form, fit or function. Changes are limited to legal manufacturer name and address and notified body. Each label will be updated at different times.

The first lot for each SKU with new legal manufacturer and notified body number is:

- 300094 – Transfer ongoing
- 300300 – Transfer ongoing
- 300400 – Transfer ongoing
- 300600 – Transfer ongoing
- 300635 – Transfer ongoing

- 300637 – Transfer ongoing
- 301155 – Transfer ongoing
- 301500 – Transfer ongoing
- 301700 – Transfer ongoing
- 301750 – Transfer ongoing
- 301900 – Transfer ongoing
- 302200 – Transfer ongoing
- 303800 – Transfer ongoing
- 304000 – Transfer ongoing
- 304100 – Transfer ongoing
- 304300 – Transfer ongoing
- 304622 – Transfer ongoing

1.4 Materials

5.1.1c

5.1.1c

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 11 May 2020, BD has not identified any chemicals in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 16 January 2020 according to Art. 59 (1,10) of the Regulation (EC) N° 1907/2006 (REACH).

1.7 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

5.1.1c

1.9 Shelf life and storage conditions

The BD Microlance™ 3 shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Microlance™ 3 have a shelf life of 5 years.

Store in a dry and warm place, not exposed to strong light.

1.5 Materials of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

5.1.1c

1.10 Standards

As per extract from the Declaration of Conformity linked to the CE certificate number 95 06 0006 CP:

Harmonized Standards	
EN 556-1:2001/ AC:2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 10993 Series	Biological evaluation of medical devices - Part 1 : 2009/ AC :2010 Evaluation and testing within a risk management process - Part 7: 2008 /AC: 2009 Ethylene oxide sterilization residuals
EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods - Part 2:2009 Test of sterility performed in the definition, validation and maintenance of a sterilization process.
EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
EN ISO 15223-1:2016	"Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements"
EN 20594-1:1993/AC:1996/A1:1997	Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment - Part 1: General requirements
Non-Harmonized Standards	
EN ISO 6009:2016	Sterile hypodermic needles for single use. Identification color coding
EN ISO 7864:2016	Sterile hypodermic needles for single use
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
UNE-EN ISO 11135:2015	Sterilization of health-care products -- Ethylene oxide
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1:2017 Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices - Part 2: 2017 Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods - Part 1:2018 Determination of a population of microorganisms on products

Note:
The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.11 Classification

BD Microlance™ Needles are classed as class IIa per Annex IX, Section III, Rule 6 of the Medical Device Directive 93/42/EEC as amended.

1.12 GMDN code

According to ISO/TS 20225 (GMDN nomenclature), BD Microlance™ 3 needles are referenced as follows:
GMDN Code: 59230
GMDN Term: Hypodermic needle, single-use, sterile

1.13 Manufacturing practices

The entire manufacturing and testing processes are following the Manufacturing Practices as specified below:

- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures.
- BD operates a system of internal and external audits to maintain compliance.
- BD confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact *(Commission Regulation EU 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact with foodstuffs")* is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- Good Manufacturing Practices as defined by the FDA Pharmaceutical is not applicable for Medical Devices.

2. Packaging

2.1 Packaging configuration

5.1.1c

[redacted]

5.1.1c

2.2 Packaging material

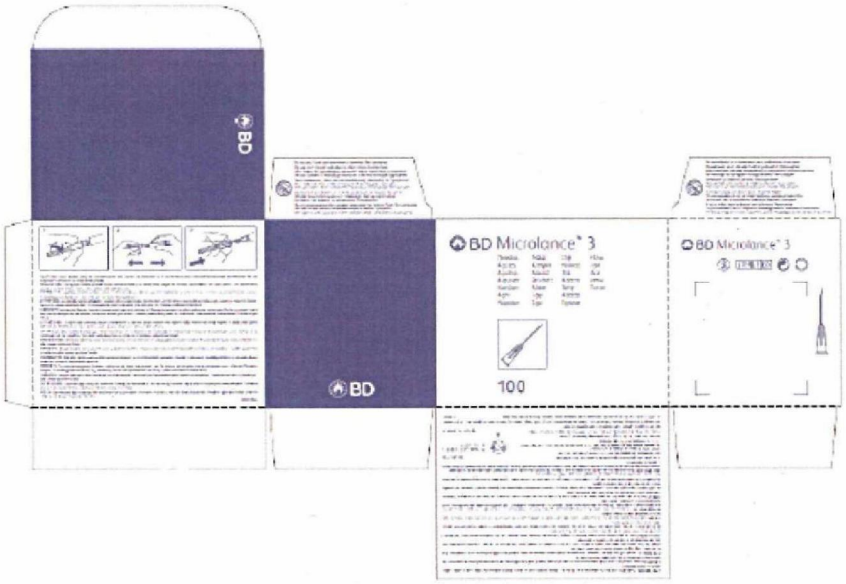
Component	Material
Unit Pack	Paper: medical use paper 60gr/m² Film: Polyamide/Polyethylene
Shelf Box	Cardboard
Shipping Case	Corrugated cardboard

2.3 Examples of labeling

Labels: According to European Medical Device directive, labels are multilingual.

Primary Packaging Label (Top Web) extracted from document DGW911 related to reference 304434:

Shelf Box extracted from document DGF341 related to reference 304434:



REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Update of 1.1: Intended use Update of 1.3: Certification Update of 1.10: Standards Update of 2.3: Examples of labeling
03	Update of 1.3: Certification

Annex 1e. Delivery Schedule

Goods will latest be ready for collection (EXW) according to the following schedule:

Annex 2 Quality Technical Agreement

Quality Technical Agreement

Quality Technical Agreement

between

the State of The Netherlands

National Institute for Public Health and the Environment (RIVM)

and

Becton, Dickinson B.V.

concerning the supply of

Syringes and (safety) needles

SUMMARY OF AGREEMENTS AND RESPONSIBILITIES		RIVM	BD
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 BD procedure current EU MDD 93/42/EEC and ISO 13485. Starting as of May 26, 2021 the new Regulation 2017/745.	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: 5.1.2c@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 2ml/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 13485 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 13485 and curent 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 possi8.	**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 or confidentiality agreement 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. Starting as of May 26, 2021 EU Regulation 2017/745, before contract undersigning or confidentiality agreement 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

Signatures

For RIVM

5.1.2e

Name: 5.1.2e
5.1.2e RIVM

Date: 10-AUG-2020

For Supplier

5.1.2e

(authorised signature)

Name: 5.1.2e
5.1.2e
EMEA, WWID Becton, Dickinson

Date: 1st Sept 2020

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

Position ☐ Qualified Person ☐ Responsible Person

Signature

This Certificate of Payment releases 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	N/A
e-mail	5.1.2e 5.1.2e @rivm.nl	e-mail	5.1.2e @europe.bd.com
telephone	+31 (0) 5.1.2e	Telephone	+31(0 5.1.2e
Function	**Logistics**	Function	**Orders**
e-mail	5.1.2e @rivm.nl	e-mail Telephone	5.1.2e @europe.bd.com +31(0 5.1.2e
Finance	5.1.2e @rivm.nl +31 (0) 5.1.2e	Finance Telephone	5.1.2e @bd.com +31(0) 5.1.2e
Function	**Qualified/Responsible Person**	Function	Product Complaints
e-mail	5.1.2e @rivm.nl	e-mail	EMEA_ 5.1.2e @bd.com
telephone	+31 (0 5.1.2e	Telephone	N/A
		Function	Service complaints
		e-mail Telephone	5.1.2e @bd.com +31 (0 5.1.2e
Function	**Product manager**	Function	5.1.2e
Name	5.1.2e	Name	5.1.2e
e-mail	5.1.2e @rivm.nl	e-mail	5.1.2e @bd.com
telephone	+31 (0) 5.1.2e	Telephone	+32 (0 5.1.2e

Quality matters
Customer Complaints

BD
Advancing the world of health

Klachtenprocedure Becton Dickinson

Bij BD hechten we veel belang aan de kwaliteit van onze diensten en producten. Daarom hebben wij een gepaste procedure ontwikkeld om u op de best mogelijke manier service te bieden bij eventuele product-gerelateerde klachten. BD heeft 3 verschillende groepen klachten. Elke groep heeft een specifieke procedure.

1 Identificatie van de correcte procedure

Service Klacht	Productklacht	Product Recall (FSCA = Field Safety Corrective Action)
Logistieke klachten bij levering zoals o.a beschadiging van producten, manco, afwijkende bestellingen... Klachten met betrekking tot de factuur zoals verkeerde klantnaam, verkeerd facturatieadres, prijsafwijkingen...	Klachten/feedback in verband met de werking of eventuele vermoedelijke gebreken van het geleverde product.	Dit is een uitzonderlijke procedure die door het bedrijf wordt gestart bij sterke vermoedens of bewijs dat een product niet naar behoren werkt. In zulke gevallen zal BD op Europees niveau beslissen een bepaald product (bepaald lotnummer) terug te roepen. Dit alles om een optimale kwaliteitszorg te waarborgen.

2 Kennisgeving van de klacht

Service Klacht	Productklacht	Product Recall
Graag melden aan onze klantendienst via: 5.1.2e @bd.com Tel BE: +32(0)53 720 556 Tel NL: +31(0)20 582 94 20	Productklachten dienen gemeld te worden via mail. Onderstaand een overzicht van de mailadressen per business unit: 5.1.2e @bd.com: Preanalytical Systems—Diabetes Care Medication Delivery Systems Medication Management Systems 5.1.2e @bd.com: Diagnostic Systems 5.1.2e @bd.com: BD Biosciences Bij vermelding van de klacht, gelieve uw BD Account Manager in copy te plaatsen. Wij verzoeken u een duidelijke omschrijving van de klacht te geven, bij voorkeur met foto's en gedetailleerde informatie over het betreffende product en lotnummer(s). Wij zullen u na kennisgeving van de klacht concrete instructies en informatie geven mbt het verdere verloop van deze procedure. (incl. het onderzoeken van het geimpacteerde staal/stalen.)	Indien deze uitzonderlijke procedure zich mocht voordoen, wordt u hiervan **schriftelijk** op de hoogte gebracht. BD wil deze informatie zo snel en efficiënt mogelijk ter beschikking stellen. Klanten die ons een andere interne recall procedure kenbaar hebben gemaakt (e-mail, fax, telefoon), zullen tevens op die wijze worden geïnformeerd.

3 Na registratie van de klacht

Service Klacht	Productklacht	Product Recall
Teneinde een nauwkeurige opvolging te garanderen wordt elke klacht meteen gelogd in ons systeem. Er wordt een klachtennummer toegekend.	De productklacht wordt door onze complaint-coördinator geregistreerd in ons systeem en krijgt een klachtennummer toegewezen. U ontvangt per e-mail een bevestiging van deze registratie. Indien er stalen/monsters voorhanden zijn, worden deze opgestuurd naar de productiesite voor verder onderzoek.	Wij informeren in een schrijven over het stopzetten van gebruik van een bepaald product. Wij vragen u om, via een specifieke procedure, de nodige acties te ondernemen en bieden u, indien mogelijk, alternatieven aan. U dient een antwoordformulier in te vullen en terug te sturen naar BD met betrekking tot de voorraad die u nog heeft van het betreffende product.

4 Onderzoek en verder verloop van de klacht

Service Klacht	Productklacht	Product Recall
Na evaluatie door onze Customer Care afdeling worden de nodige stappen ondernomen. U wordt hiervan op de hoogte gehouden. De klacht wordt uiteindelijk door onze Customer Care afdeling afgesloten na volledige afhandeling van het probleem.	Onze kwaliteitsafdelingen op de verschillende productiesites onderzoeken nauwkeurig uw klacht. Men doet uitgebreide tests op de beschikbare stalen/monsters en gaat de historiek na van de geïmpacteerde loten. Er wordt een risicoanalyse gemaakt en men bepaalt de ernst van het probleem. Op basis van de onderzoeksresultaten wordt de klacht al dan niet bevestigd en wordt actie ondernomen. Ons hoofddoel is om gelijkaardige incidenten in de toekomst te vermijden. Onze klachtenafdeling stuurt u na definitieve conclusie een communicatie over de evaluatie van uw klacht.	De QA/RA (Quality/Regulatory Afdeling)verantwoordelijke registreert uw antwoordformulier en maakt het over aan de plaatselijk bevoegde overheidsinstanties. De producten worden door onze Customer Care afdeling retour genomen, gecrediteerd of vervangen.