"CODAN"
Sterile syringes

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Product specification – "CODAN" sterile syringes

Contents

Revision History

Revision	Date	Description
01	14 January 2019	Initial issue
02	12 August 2019	Update of Requirements: deleted former point 17, added product
03	21 April 2021	New name of Notified Body, CE number, added text on Polymer Additives, BSE, Phthalates, Bisphenol-A and -F, Biocompatibility, updated standards, Classification, Shelf Life, Dead Space
04	08 September 2022	New legislation: MDR 2017/745 New Notified Body name (DNV Product Assurance AS) Update of standards Added plunger material polyethylene and sterility expiry

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Document Guidance

The information in this document shall be treated as confidential between CODAN Medical ApS and our designated OEM customers and supersedes any previous Product Description, Specification and/or drawings provided by CODAN Medical ApS. This document is not to be provided to any third party. This information is not to be used for registration. If product information is required for Customer's registration with a health authority, the customer must request a formal Letter of Authorization.

Introduction

CODAN Medical ApS operates and maintains a Quality Management System in all participating production facilities in accordance with the regulations of EN ISO 13485:2016 (Medical Devices – Quality Management Systems – Requirements for regulatory purposes). Additionally, CODAN Medical ApS operates and maintains a system in all participating CODAN Medical ApS production facilities that ensures the implementation of the requirements set out in EU Regulation 2017/745.

The Notified Body "DNV GL Presafe AS" (Identification No. 2460) certifies CODAN Medical ApS.

The effectiveness of the Quality Management System is reviewed by the Notified Body on a yearly basis. All CODAN Medical ApS products are manufactured under equivalent production and inspection conditions ensuring that all products have the same high-quality level.

All processes required by the EU Regulation 2017/745 and DS/EN ISO 13485:2016 (e.g., Validation, Risk Management, Clinical Evaluation, Technical Documentation, Essential Requirements) are covered by the certification for CODAN Medical ApS medical devices. These documents are confidential and not disclosed to others than competent authorities and our Notified Body.

This product specification describes the properties and the materials of the designated product. The product is manufactured and supplied in accordance with the effective requirements.

Products, which are distributed and used in accordance with other regulations, are passing through a development and production process that meets these deviating requirements in coordination with the customers.
The same applies to products to be manufactured in accordance with the customers' specifications.

The manufacturing process comprises several manufacturing steps, which are performed in accordance with written manufacturing specifications. The materials used in each production lot are documented according to types, quantities, and origin lots.

The plastic components are manufactured in an injection moulding process, assembled and the completed product is packed in single-unit peel packages.

The last step of the manufacturing process for sterile products is the sterilization in a validated process.

Regulation (EC) No. 1907/2006 – REACH

The EU chemicals regulation 1907/2006 – REACH – came into force on June1, 2007. As a manufacturer of medical devices, CODAN Medical ApS is a downstream user according to REACH without the obligation of registering any chemicals. We are in close contact with our suppliers to ensure that all starting materials used for our products are further on available.

A substantial goal of REACH is the safe use of substances, preparations and articles. Therefore, it is necessary that the relevant information is passed on in the supply chain. We comply with our obligations according to REACH to inform our customers about the presence in our articles of any substance of very high concern (SVHC) as per ECHA candidate list.

Based on the information obtained from our suppliers we can confirm that in our current production we do not use any substance of very high concern in a concentration above 0.1 % (w/w) as per current ECHA candidate list. If our suppliers inform us of presence of any SVHC substances, we will inform our customers accordingly.
In conformance with the REACH regulation, we do not provide any safety data sheets for our products.

RoHS Directive 2011/65/EU

The European directive 2011/65/EU dated June 8, 2011, previously 2002/95/EC, on the restriction of use of certain hazardous substances in electrical and electronic equipment, defines maximum concentration values for certain substances as per annex II of the directive valid for medical devices placed onto the market since July 22, 2014.

The products manufactured by CODAN Medical ApS do not require electric current or electromagnetic fields for proper function and thus the directive is not applicable to our products. Nevertheless, we can confirm that according to the information obtained from our suppliers, the RoHS limiting values for lead, hexavalent chromium, mercury, cadmium, PBB and PBDE are not exceeded in the materials used for our products.

Latex

According to the information obtained from our suppliers, latex is not intentionally used in the formulation and/or the manufacturing process of our products marked latex-free. Therefore, these substances are not expected to be present in the product in concentrations above 0.1 % w/w. However, our raw material suppliers do not routinely perform analysis for these chemicals.

Polymer Additives and BSE

Our single-use medical devices consist mainly of resins. The documentation presented by our suppliers shows that

- No material of animal origin has been used
- Material of animal origin in the starting materials is in compliance with applicable food contact regulations in Europe and USA

- Suppliers have moved to vegetable-based sources or are sourcing their raw material from countries with lower risk
- Production of animal-derived additives used in raw materials which are categorized as category 3 according to the Regulation (EC) 1069/2009, the Regulation (EC) 1069/2009 and Regulation 142/2011, or come from countries considered as BSE-free
- The production location of these additives is approved as category 3 oleo chemical plants by local Authorities, and the production has received the associated certification with registration number. The treatment of beef tallow requires high temperature (under pressure or not) for a specified duration, as defined by the Regulation 142/2011, to eliminate the risk of BSE contamination
- According to OMS/CDS/VPH/195.45 BSE has never been found in beef tallow. Moreover, WHO claims that tallow does not represent a risk for human and animal health
- Furthermore, the final product is obtained through palletization then conversion, during which the polyolefin plastics are exposed to shearing stress and temperatures from 160°C to 300°C in a period of 20 seconds to a few minutes.
- We do not use any material of animal origin in our production of medical devices

Based on information received from our suppliers and on our knowledge of internal production processes we consider it unlikely for our medical devices to present any risk of TSE or BSE.

Phthalates

Our single-use medical devices consist mainly of resin. The documentation presented by our suppliers show that **Phthalates** are not used as additives or raw materials in the manufacture of this grade.

On basis of information received from our suppliers, we consider it unlikely that our syringes should contain traces of Phthalates or present any risk in this respect.

Bisphenol-A and Bisphenol-F

Our single-use medical devices consist mainly of resin. The documentation presented by our suppliers show that **none of the Bisphenol-A and Bisphenol-F substances** is used as additives or raw materials in the manufacture of this grade.

On basis of information received from our suppliers, we consider it highly unlikely that our syringes present any risk of containing Bisphenol-A and Bisphenol-F substances.

Biocompatibility

Our single-use medical devices comply with the requirements of the standard for bio-compatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

Requirements, Standards, Rules (if applicable to the product)

1. DS/EN ISO 13485:2016
2. Compliance with FDA QSR 21 CFR §820
3. Compliance with Danish Health Protection Agency
4. Compliance with Danish Law on Medical Devices
5. Compliance with MEDDEV 2.12-1
6. European Pharmacopoeia: Section 2.6.14. Bacterial Endotoxins
7. Regulation (EC) No. 1907/2006 - REACH
8. Directive 93/42/EEC and Regulation 2017/745 for medical devices: The CODAN Medical ApS products comply with the essential requirements of the directive and the regulation. The conformity of the products is audited and certified by a notified body. The products covered by the directive can be marked with the CE mark
9. DS/EN ISO 556-1:2001: Sterilization of medical devices – Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilized medical devices
10. DS/EN ISO 868-5:2018: Packaging materials and systems for medical devices which are to be sterilized
11. DS/EN ISO 868-6:2017: Packaging materials and systems for medical devices which are to be sterilized
12. DS/ISO 2859, part 1 + Cor.1:2001: Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by lot inspection
13. DS/EN ISO 7886-1:2018: Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
14. DS/EN ISO 10993-1:2020: Biological evaluation of medical devices, part 1: Evaluation and testing within a risk management system, table A.1 - Evaluation tests for consideration: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Haemocompatibility
15. DS/EN ISO 10993-1:2009: Biological evaluation of medical devices, part 1: Evaluation and testing within a risk management system, table A.1 - Evaluation tests for consideration: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Haemocompatibility
16. DS/EN ISO 10993-7:2008: Biological evaluation of medical devices, part 7: Ethylene oxide sterilization residuals
17. DS/EN ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of sterilization process for medical devices
18. DS/EN ISO 11138-1:2017: Sterilization of health care products – Biological indicators – Part 1: General requirements
19. DS/EN ISO 11138-2:2009: Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
20. DS/EN ISO 11607-1:2019: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
21. DS/EN ISO 11607-2:2019: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

22. DS/EN ISO 11737-1:2006: Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
23. ISO 11737-2:2019: Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
24. DS/EN ISO 14644-1:2015: Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness
25. DS/EN ISO 14644-2:2015: Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
26. DS/EN ISO 14644-4:2001: Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up
27. DS/EN ISO 14971:2012: Medical devices – Application of risk management to medical devices
28. DS/EN ISO 15223-1:2021: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
29. DS/EN ISO 80369-7.2021: Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications.
30. BS/EN 62366:2015: Medical Devices – Application of usability engineering to medical devices

Products

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.1912	0.5 ml	Luer centric	Clear	White	100	3,200

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.1612	1 ml	Luer centric	Clear	White	100	3,200
62.1614	1 ml	Luer centric	Clear	White	100	3,200
62.1640	1 ml	Luer centric	Clear	White	100	3,200
62.1657	1 ml	Luer centric	Clear	White	100	3,200

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.2611	2 ml	Luer centric	Clear	White	100	3,200
62.2659	2 ml	Luer centric	Clear	White	100	3,200

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.2637	2,5 ml	Luer lock	Clear	White	100	3,200

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.3623	3 ml	Luer centric	Clear	White	100	3,200
62.3760	3 ml	Luer lock	Clear	White	100	3,200

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.4606	5 ml	Luer centric	Clear	White	100	1,600
62.4717	5 ml	Luer lock	Clear	White	100	1,600
62.4725	5 ml	Luer lock	Clear	Red	100	1,600
62.5605	5 ml	Luer excentric	Clear	White	100	1,600
62.5607	5 ml	Luer excentric	Clear	White	100	1,600

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.6610	10 ml	Luer excentric	Clear	White	100	1,200
62.6616	10 ml	Luer excentric	Clear	White	100	1,200
62.6703	10 ml	Luer lock	Clear	White	100	1,200
62.6706	10 ml	Luer lock	Clear	White	100	1,200
62.6708	10 ml	Luer lock	Clear	White	100	1,200
62.6734	10 ml	Female luer lock	Clear	White	100	1,200

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.7602	20 ml	Luer excentric	Clear	White	50	800
62.7704	20 ml	Luer lock	Clear	White	50	800
62.7709	20 ml	Luer lock	Clear	White	50	800

Product no.	Capacity	Description	Colour cylinder	Colour plunger	Units per carton	Units in shipping box
62.8426	50 ml	Luer lock	Clear	White	25	300
62.8436	50 ml	Catheter tip	Clear	White	25	300
62.8437	50 ml	Luer excentric	Clear	White	25	300
62.8438	50 ml	Catheter tip	Clear	White	25	300

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Classification

Class I, sterile syringes with a measuring function, Medical Device under Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended and Regulation 2017/745 Annex VIII, chapter III, section 4.2.

Components, Materials

Prior to initial release for production, all raw materials and components for use in the fluid path are subjected to a material qualification procedure to assess their suitability with regard to biocompatibility and technical performance.

Particularly, compliance with the aforementioned requirements is checked. Only materials and components that meet these requirements and additionally pass our current incoming inspections are used in production.

CODAN Medical ApS is obligated to inform all customers of any material and technical changes; however, in case of a changeover to another supplier for equal materials that conform to the effective standards as well, notification will not be given. Neither will notification be given if technical changes and product improvements are made, which do not compromise the use of the products.

Component	Material
Cylinders	Polypropylene
Plunger	Polypropylene / white masterbatch polyethylene
Silicone ring	Silicone rubber
Lubricant	Medical grade silicone oil
Single-unit package	Sealing paper
	Sealing foil
Inner cartons	Cardboard – not corrugated
Shipping box	Corrugated

Packaging and Labelling

A) Single-unit package

The syringes are sealed in a peel pack and CE-marked for human use. The syringes are packed in one inner box.

B) Shipping box

Please refer to the list of products for the number of inner cartons packed into a corrugated shipping box. Each shipping box is provided with an indicator, which by change of colour proves that the goods successfully passed the sterilization process.

Shipping boxes are packed on one-way-pallets and stretch-wrapped for protection against damages to the boxes and from weather conditions.

Shelf life

Shelf life is 4 years and 11 months. No special storage or transportation conditions are required. It is recommended to store the products at room temperature in a dry place and not exposed to strong light.

Sterilization

For the sterilization of this product, CODAN Medical ApS uses Ethylene Oxide. The sterilization process has been subjected to a technical and microbiological validation in accordance with the regulations of DS/EN ISO 11135, part 1 (Sterilization of health care products – Ethylene Oxide). At the given physical parameters, a sterility assurance level (SAL) of at least 10^{-6} is obtained.

To prove the effectiveness of the sterilization, process bioindicators according to DS/EN ISO 11138, part 1 and part 2 are used for each sterilization run.

In order to reduce the residual content of ethylene oxide, special degassing cycles are integrated in the sterilization process. After completion of the sterilization process, the products are kept in a quarantine area for 2 days.

The tests for ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals are performed according to EN ISO 10993-7, 4.4.6.2 (simulated use, water extraction method) and the products meet the requirement of ≤ 2 mg for prolonged exposure devices.

Expected Product Life Span in Storage

The expiry date for sterile products is 4 years and 11 months from date of production. Handling and storage conditions vary widely, thus it is up to the end user to determine if degradation or damage has occurred in storage or transit prior to use.

Queries

For any product queries please contact our Customer Service via e-mail: sales@codanmedical.dk

Disposal

According to information obtained from our suppliers, our medical devices are suited for disposal into incinerators.

Test Programme

The following tests and controls are part of the CODAN Medical ApS programme for ensuring the product quality:

1. Type tests for the qualification of purchased materials and components
2. Incoming inspections to prove the identity and the compliance with the materials' properties, dimensions and tolerances as agreed with the supplier
3. In process controls set in accordance with internal criteria, comprising integrated manufacturing controls and controls for acceptance on the basis of random samples between the different manufacturing stages
4. Functional tests performed by the quality control on random samples from moulding to finished products
5. Visual finished product inspections performed on random samples according to internal specifications
6. Efficiency control of the sterilization (sterilization process monitoring) by means of bioindicators
7. Tests for bacterial endotoxins on the basis of the regulations of the European Pharmacopoeia
8. Tests for ethylene oxide residues and bioburden testing are periodically performed
9. Bacteriological controls of the manufacturing environment

Dead Space (maximum) according to ISO 7886-1

Syringe size ml	0.5	1	2	2.5	3	5	10	20	50	60
Dead space ml	0.07	0.07	0.07	0.07	0.07	0.075	0.10	0.15	0.20	0.20