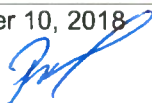



50 ml Catheter tip Sterile

| | | |
|-------------------------|---|--|
| Approval date/signature | Workshop Manager Poul Nielsen | October 10, 2018  |
| Approval date/signature | Quality Assurance Manager Tine Bendsen | October 10, 2018  |

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| Revision | Date | Description |
|----------|------------------|---------------|
| 01 | October 10, 2018 | Initial issue |

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Introduction

CODAN Medical ApS established and maintains a Quality Management System in all participating production facilities in accordance with the regulations of EN ISO 13485:2012/AC:2012 (Medical Devices – Quality Management Systems – Requirements for regulatory purposes). Additionally CODAN Medical ApS established and maintains a system in all participating CODAN Medical ApS production facilities that ensures the implementation of the requirements set out in Council Directive 93/42/EEC on medical devices (MDD).

This is certified by our Notified Body “Presafe Denmark A/S” (Identification No. 0543).

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 Council Directive 93/42/EEC on medical devices and DS/EN ISO 13485:2012/AC:2012 (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.

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Regulation (EC) No. 1907/2006 – REACH

The EU chemicals regulation 1907/2006 – REACH – came into force on June 1, 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 of any substances of very high concern (SVHC) as per ECHA candidate list in our articles.

Based on the information obtained from our suppliers we can confirm that we do not use any substances of very high concern in a concentration above 0.1 % (w/w) as per current ECHA candidate list in our current production. If our suppliers inform us of the 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 the use of certain hazardous substances in electrical and electronic equipment defines maximum concentration values for certain substances as per annex II of the directive that are 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, analysis for these chemicals is not routinely performed by our raw material suppliers.

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

1. DS/EN ISO 13485:2012
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. Compliance with Proclamation no 1263 of 15. December 2008
7. European Pharmacopoeia: Section 2.6.14. Bacterial Endotoxins
8. Regulation (EC) No. 1907/2006 - REACH
9. Directive 93/42/EEC for medical devices: The CODAN Medical ApS products comply with the essential requirements of the directive. 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
10. 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
11. DS/EN ISO 868-3-7:2009: Packaging materials and systems for medical devices which are to be sterilized
12. DS/EN ISO 1707:1997: Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings
13. 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
14. DS/EN ISO 7886-1:2018: Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
15. DS/EN ISO 7886-2:1997: Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps
16. 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
17. DS/EN ISO 10993-7:2008: Biological evaluation of medical devices, part 7: Ethylene oxide sterilization residuals
18. European Pharmacopoeia: Section 2.6.14. Bacterial Endotoxins
19. 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
20. DS/EN ISO 11138-1:2017: Sterilization of health care products – Biological indicators – Part 1: General requirements
21. DS/EN ISO 11138-2:2009: Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
22. DS/EN ISO 11607-1:2009: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
23. DS/EN ISO 11607-2:2006: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
24. DS/EN ISO 11737-1:2006: Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products

25. ISO 11737-2:2009: Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
26. DS/EN ISO 14644-1:2015: Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness
27. 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
28. DS/EN ISO 14644-4:2001: Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up
29. DS/EN ISO 14971:2012: Medical devices – Application of risk management to medical devices
30. DS/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
31. DS/EN ISO 20594-1:1994: Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements
32. BS/EN 62366:2008: Medical Devices – Application of usability engineering to medical devices

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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 have additionally passed 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 realized that do not compromise the use of the products.

| Component | | |
|---------------|--------------|-----------------|
| Cylinder | Cone | Catheter tip |
| | Material | Polypropylene |
| | Colour | Natural clear |
| | Master batch | None |
| Plunger | Material | Polypropylene |
| | Colour | White |
| Adaptor | Material | Polypropylene |
| | Colour | Red |
| Lubricant | | Silicone oil |
| Silicone ring | Material | Silicone rubber |
| | Colour | Black |
| Scale | Range | 50 ml |
| | Graduation | 1 ml |
| | Colour | Green |

Packaging and Labelling

A) Single-unit package

The syringes are sealed in a peel pack. The print of the sealing paper provides labelling data following the directive 93/42/EEC (appendix I). 25 syringes are packed in one inner box.

B) Shipping container

12 inner boxes are packed into a shipping carton. Each shipping carton is provided with an indicator, which proves by change of the colour that the goods passed the sterilization process.

Shipping cartons are packed on a one-way-pallet and stretch-wrapped for protection against damages of the cartons and atmospheric effects.

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 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.

Disposal

According to the information obtained from our suppliers, the disposal of our medical devices in incinerators is possible.

Test Program

The following tests and controls are part of the CODAN Medical ApS program to ensure 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 sterilisation (sterilisation 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

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Drawing

The following drawing is part of this product specification. The drawings must not be duplicated or disclosed to others unless expressly authorized by CODAN Medical ApS. The recipient or a third party are in no way allowed to use them improperly.

