



EC Certificate

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

Certificate No.:
DGM – 693

Reference:
aur5a2003v270f731

Date of issue:
2021-03-15

Valid Until:
2024-05-26

Initial date of issue:
2010-04-27

This is to certify that the quality system of:

Nunc A/S
(Thermo Fisher Scientific Roskilde Site)
Kamstrupvej 90
4000 Roskilde
Denmark

has been audited under the requirements of:

Annex V, section 3.2 - Production Quality Assurance, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex V.

The scope of the certification is:

Manufacturing of dishes and tubes in class IIa for handling of In Vitro Fertilization and handling and transportation for diagnostic use

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. This EC certificate is issued pursuant to the Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the MDD, Annex V, section 4.

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

Bent Buus
Authorized person

For Presafe Denmark A/S



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The following product(s)/product families in class IIa are covered by the certificate:

Tube and Dishes for In Vitro Fertilization and diagnostic use