EC Certificate
Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding section 4

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 877	**aur2a2104v470f385**	**2021-04-14**	**2024-05-26**	**2016-04-15**

This is to certify that the quality system of:

DDD-Diagnostic A/S
Kærvej 12
2970 Hørsholm
Denmark

has been audited under the requirements of:

Annex II, Full quality assurance system, excluding section 4, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex II. For the placing on the market of class III products covered by this certificate an Annex II section 4 certificate is required.

The certificate covers the following devices:

Design, manufacture, and final inspection of gamma cameras in class IIa

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 in accordance with 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 II, section 5.

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:

Product family	**GMDN Code**
Gamma cameras	40640