



Quality System Certificate

Certificate No.:
DGM – 509

Reference:
aur2a1902v420f385

Date of issue:
2019-03-29

Valid Until:
2021-02-09

Initial date of issue:
2006-02-14

This is to certify that the quality system of:

DDD-Diagnostic A/S
Kærvej 12
2970 Hørsholm
Denmark

fulfills the requirements in:

DS/EN ISO 13485:2016 and EN ISO 13485:2016

The certificate covers the following activities:

Design, development, production, installation and servicing of gamma cameras

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001:2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Bent Buus

Authorized person

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

For Presafe Denmark A/S