



A DNV & NEMKO
COMPANY

Quality System Certificate

Certificate Number:

DGM - 509

This is to certify that the quality system of:

DDD-Diagnostic A/S

Dr. Neergaards Vej 5E
2970 Hørsholm
Denmark

fulfills the requirements in:

DS/EN ISO 13485:2012 and EN ISO 13485:2012

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 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the applicable corrigenda. 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

For Presafe Denmark A/S

Date of issue: 2015-02-10
Expires: 2018-02-10
Initial date of issue: 2006-02-14
Reference: aur2a1411v320f385

Presafe Denmark A/S

Tuborg Parkvej 8
2900 Hellerup
Denmark



Additional sites covered by the certificate:

**Kogle Alle 1
2970 Hørsholm
Denmark**

COPY

Certificate number: DGM – 509
Certificate type: Quality System Certificate

Date of issue: 2015-02-10
Expires: 2018-02-10
Initial date of issue: 2006-02-14
Reference: aur2a1411v320f385

Presafe Denmark A/S

Tuborg Parkvej 8
2900 Hellerup
Denmark