



EC Certificate

Certificate Number: DGM - 877

This is to certify that the quality system of:

DDD-Diagnostic A/S
Kærvej 12
2970 Hørsholm
Denmark

has been approved in conformity with the requirements of:

Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

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

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions of 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 Directive.


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2018-01-12
Expires: 2021-04-15
Initial date of issue: 2016-04-15
Reference: aur2a1712v400f385



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

DGM

Page 1 of 2



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

Gamma cameras

Certificate number: DGM – 877
Certificate type: EC Certificate

Date of issue: 2018-01-12
Expires: 2021-04-15
Initial date of issue: 2016-04-15
Reference: aur2a1712v400f385



DGM

Page 2 of 2


Product List

The following products are covered by DGM – 877:

Product	ID	Class	Date for placing on the market (with CE Mark)	Product family on DGM – 877 covering the device
SoloMobile	9SOL2210	Ila	2016-04-15	Gamma cameras
Solo	9SOL2225	Ila	2016-04-15	Gamma cameras
CorCam	9COR2370	Ila	2016-04-15	Gamma cameras
QuantumCam	9SYS2070	Ila	2016-04-15	Gamma cameras
NephroCam	9KID2275	Ila	2016-04-15	Gamma cameras

"The products on this list have been accepted by Presafe Denmark A/S"

Date: 2016-04-15

Name and signature: Bent Buus 

Title: Lead auditor