

This is to certify that the quality system of:

**DDD-Diagnostic A/S**  
**Dr. Neergaards Vej 5E**  
**2970 Hørsholm**  
**Denmark**

has been approved in conformity with the requirements of:

**Annex II, section 3.2 - Full quality assurance system**

of Council Directive 93/42/EEC concerning medical devices as 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**

The EC 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. This EC certificate is issued pursuant to the Presafe Denmark A/S' terms and conditions for the certification of 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 as per the Directive.



**Carsten Worm Jensen**  
Authorized person

Date of issue: 2016-04-15  
Expires: 2021-04-15  
Initial date of issue: 2016-04-15  
Reference: tdr2a1501v332f385

The following product in class IIa is covered by the certificate:

**Gamma cameras**

Certificate number: DGM – 877  
Certificate type: EC Certificate

Date of issue: 2016-04-15  
Expires: 2021-04-15  
Initial date of issue: 2016-04-15  
Reference: tdr2a1501v332f385


## 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