EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until
10000379464-PA-NA-DNK Rev 0.0	PRJN-189369-2020-PA-DNK	26 May 2024

This is to certify that the quality system of:

DDD-Diagnostic A/S

Kærvej 12, 2970 Hørsholm, Denmark

For design, production and final product inspection/testing of:

GAMMA CAMERAS

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 06 May 2021

Check Validity

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Eugenie Winger Husebye
Technical Reviewer

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM-877 to DNV GL Presafe A/S (NB 2460)	06 May 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Gamma cameras	SoloMobile	IIa
	Solo	
	CorCam	
	NephroCam	
	CardioMD IV	
	QuantumCam	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
DDD-Diagnostic A/S	Kærvej 12, 2970 Hørsholm, Denmark

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate