EC CERTIFICATE

Number: 2122022CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Spectrum Dynamics Medical Ltd.

22 Bareket Street
North Industrial Park
P.O. Box 3033
Caesarea 3088900
Israel

For the product category(ies)

Single Photon Emission Computed Tomography (SPECT) systems and Combined Single Photon Emission Computed Tomography and Computing Tomography (SPECT/CT) systems

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2122022CN, initially dated 21 January 2009
Addendum, initially dated 21 January 2009

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 January 2023
Issued for the first time: 21 January 2009
Revised: 18 February 2019
Reissued: 1 January 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2122022CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Single Photon Emission Computed Tomography (SPECT) systems and Combined Single Photon Emission Computed Tomography and Computing Tomography (SPECT/CT) systems

Issued to:

Spectrum Dynamics Medical Ltd.
22 Bareket Street
North Industrial Park
P.O. Box 3033
Caesarea 3088900
Israel

This certificate covers the following product(s):

- D-SPECT® system (class IIa) for Cardiac applications
- D-SPECT® L system (class IIa) for Cardiac applications
- D-SPECT Processing and Reviewing Workstation (class IIa) for Cardiac applications
- VERITON™ NM system (class IIa) for whole body scanning applications
- VERITON CT system (class IIb) for whole body and CT scan applications

Initial date: 21 January 2009
Revision date: 19 November 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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EC sertifikatas

Nr: 2122022CE01

Pilna kokybės užtikrinimo sistema

93/42/EEC-Medicinos Prietaisų Direktyva, Priedas II (išskyrus 4)

(IIa, IIb arba III klasės įrenginiai)

Gamintojas:

Spectrum Dynamics Medical Ltd.

22 Bareket Street

North Industrial Park

P.O. Box 3033

Caesarea 3088900

Israel

Taikomas šiai produktų kategorijai:

Vieno fotono emisijos kompiuterinės tomografijos sistemos (SPECT) ir kombinuotos vieno fotono emisijos kompiuterinės tomografijos sistemos ir kompiuterinės tomografijos sistemos (SPECT/CT)

Dekra suteikia teisę naudoti žemiau nurodytą Notifikuotos Institucijos Identifikacinį Numerį žymėti CE Atitiktį produktams, kurie atitinka reikalaujamą techninę dokumentaciją ir jiems taikomas Direktyvos nuostatas:

0344

Dokumentai, sudarantys šio sertifikato pagrindą:

Sertifikavimo pranešimas 2122022CN, pirminė data 2009 m. sausio 21 d.

Priedas, pirminė data 2009 m. sausio 21 d.

Šis sertifikatas galioja iki:	**2023 m. sausio 1 d.**
Pirmą kartą išduotas:	**2009 m. sausio 21 d.**
Peržiūrėtas:	**2019 m. vasario 18 d.**
Išduotas pakartotinai:	**2018 m. sausio 1 d.**

Priedas

Priklausantis sertifikatui: 2122022CE01

CE ATITIKTIES PATVIRTINIMAS

MEDICININIAI PRIETAISAI

Vieno fotono emisijos kompiuterinės tomografijos sistemos (SPECT) ir kombinuotos vieno fotono emisijos kompiuterinės tomografijos sistemos ir kompiuterinės tomografijos sistemos (SPECT/CT)

Išduotas:

Spectrum Dynamics Medical Ltd.

22 Bareket Street

North Industrial Park

P.O. Box 3033

Caesarea 3088900

Israel

Šis sertifikatas apima tokius produktus:

D-SPECT® sistema (IIa klasės) taikymui kardiologijoje

D-SPECT® L sistema (IIa klasės) taikymui kardiologijoje

D-SPECT Processing and Reviewing Workstation darbo stotis (IIa klasė) taikymui kardiologijoje

VERITON™ NM sistema (IIa klasės) viso kūno skenavimo tyrimams

VERITON CT sistema (IIa klasės) viso kūno ir kompiuterinės tomografijos skenavimo tyrimams

Pirmą kartą išduotas:	**2009 m. sausio 21 d.**
Peržiūrėtas:	**2018 m. lapkričio 19 d.**