# EC CERTIFICATE

Number: 2172702CE02

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**
(Devices in Class IIa, IIb or III and Devices in Class I with measuring function)

Manufacturer:

## Quirem Medical BV

**Zutphenseweg 55**
**7418 AH Deventer**
**The Netherlands**

For the product category(ies)

**Image processing software to determine the radiation absorbed dose following treatment with Holmium microspheres and support planning and verification of selective internal radiation therapy treatment**

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 2172702CN, initially dated 1 April 2015**
**Addendum, initially dated 10 February 2017**

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, that covers the aspects of manufacture concerned with the conformity of the devices with metrological requirements, for the above mentioned product category in accordance to the provisions of Annex II 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 April 2023
Issued for the first time: 10 February 2017
Revised: 6 August 2020
Reissued: 1 April 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
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2172702CE02 

# CE MARKING OF CONFORMITY
## MEDICAL DEVICES

Image processing software to determine the radiation absorbed dose following treatment with Holmium microspheres and support planning and verification of selective internal radiation therapy treatment

Issued to:

**Quirem Medical BV**
**Zutphenseweg 55**
**7418 AH Deventer**
**The Netherlands**

This certificate covers the following product(s):

- Q-Suite 2.x
- Q-Suite, version 1.x

Initial date: 10 February 2017
Revision date: 28 May 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager



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