

Number: 2256584CE01

# EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

**Quirem Medical B.V.**

Zutphenseweg 55

7418 AH Deventer

The Netherlands

SRN ID.: NL-MF-000006753

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 EU- Regulation which apply to them:

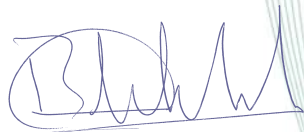
## 0344

**Supplement to certificate: 2172702CN**

**Additional certificate: 2256584TD01**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M.A. McKenzie  
Principal Certification Manager

First Issued: **4 April 2023**

Date: **4 April 2023**

Expiry date: **1 April 2028**

© Integral publication of this certificate and adjoining reports is allowed

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 [www.dekra.nl](http://www.dekra.nl) Company registration 09085396



Number: 2256584CE01

# EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

**Class III**

**Group of Devices:**

QuiremSpheres

QuiremScout

QuiremSpheres Customer Kit (PN: QS-C001)

First Issued: 4 April 2023

Date: 4 April 2023

Expiry date: 1 April 2028

© Integral publication of this certificate and adjoining reports is allowed

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 [www.dekra.nl](http://www.dekra.nl) Company registration 09085396



Number: 2256584CE01

# EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Conditions for or limitations to the validity of this certificate:

- N/A

## Certificate History

*Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.*

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	04-04-2023	2172702CN33	First issue

First Issued: 4 April 2023

Date: 4 April 2023

Expiry date: 1 April 2028

© Integral publication of this certificate and adjoining reports is allowed

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 www.dekra.nl Company registration 09085396