

Number: 2256584TD01

# EU Technical Documentation Assessment Certificate

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

Manufacturer:

**Quirem Medical B.V.**

Zutphenseweg 55

7418 AH Deventer

The Netherlands

SRN ID.: NL-MF-000006753

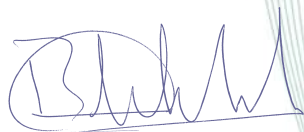
DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

## 0344

**Supplement to certificate: 2172702CN**

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**

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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



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This certificate covers the following device(s):

|   |  |
|---|--|
| <b>Class III</b>  |  |
| <b>Basic UDI-DI:</b> 8719266QS-V001ZV<br><b>Device Name:</b> QuiremSpheres<br><b>Type:</b> Active-Implantable Devices - Others (class III, J99)<br><b>Model:</b> QS-V001  | <i>Intended Purpose:</i><br>QuiremSpheres is intended for implantation into hepatic tumours by delivery via the hepatic artery for the treatment of patients with unresectable liver tumours.                      |
| <b>Basic UDI-DI:</b> 8719266QS-S001Z8<br><b>Device Name:</b> QuiremScout<br><b>Type:</b> Active-Implantable Devices - Others (class III, J99)<br><b>Model:</b> QS-S001  | <i>Intended Purpose:</i><br>QuiremScout is intended for evaluating lung shunt, extrahepatic deposition and intrahepatic distribution of microspheres injected in the hepatic artery in patients eligible for SIRT. |
| <b>Basic UDI-DI:</b> 8719266QS-C001VQ<br><b>Device Name:</b> QuiremSpheres Customer Kit (PN: QS-C001)<br><b>Type:</b> Devices for Administration, Withdrawal And Collection – Other (class III, A99)<br><b>Model:</b> QS-C001 | <i>Intended Purpose:</i><br>QuiremSpheres is intended for implantation into hepatic tumours by delivery via the hepatic artery for the treatment of patients with unresectable liver tumours                       |

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## 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 |

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