

1 Issuer's name and address

Name : Quirem Medical B.V.
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 Website : <https://www.quirem.com/>
 Email : info.quirem@terumo-europe.com

This EU Declaration of Conformity is issued under the sole responsibility of Quirem Medical B.V.

2 Object of the declaration

We hereby declare that the CE-marked medical devices, within the product group, conform to European Medical Device Regulation MDR 2017/745. The EU technical documentation assessment certificate and EU quality assurance certificate with reference numbers are listed below, the certificates are issued by DEKRA Certification B.V., Notified Body Identification Number 0344, in accordance with conformity assessment route Annex IX of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Relevant certificate(s)	Product name	EMDN code	Classification & rule MDR Annex VIII	Basic UDI-DI
2256584TD01	QuiremSpheres	J99	Class: III Rule: 8 and 9	8719266QS-V001ZV
Relevant certificate(s)	Accessory name	EMDN code	Classification & rule MDR Annex VIII	Basic UDI-DI
2256584TD01	QuiremSpheres Customer Kit	A99	Class: III Rule: 8 and 9	8719266QS-C001VQ

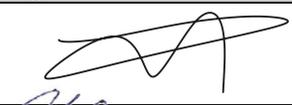
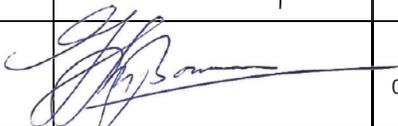
3 Quality Management System

In addition, the QMS of Quirem Medical BV is certified by Dekra Certification BV to EN ISO 13485:2016:

Certification number	Scope
2256584CE01 (Supplement to certificate 2172702CN)	Design, manufacturing and distribution of radioactive microspheres and planning/support image software used for Radio Embolization in the area of radiology and radiotherapy.

4 Signature

This EU Declaration of Conformity is signed for and on behalf of Quirem Medical BV.

	Name	Function	Signature	Date
Approved by:	L. Domas	VP Global Interventional Oncology Strategy and Therapy Development		9-May-2023
Approved by:	H. Bouman	QA/RA Manager		09-MAY-2023