Declaration of Conformity EU-MDR 2017/745 Q-Suite 2.2

ID. 1103-2.2-004-02

1 Issuer's name and address

Name	:	Quirem Medical B.V.
SRN	:	NL-MF-000006753
Address	:	Zutphenseweg 55 7418 AH Deventer The Netherlands
Phone	:	+31 (0)85 040 4170
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 device, within the product group, conforms 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
2266115CE01	Q-Suite 2.2	Z119092	Class: IIb Rule: 11	8719266QS-Q002YU

3 Quality Management System

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

Certification number	Scope
2172692	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:	K. Verhaert	VP Quality, Regulatory & Vigilance		10-DEC-2024