DECLARATION OF CONFORMITY

We, the company
RoweMed AG - Medical 4 Life
Juri-Gagarin-Ring 4
19370 Parchim
Germany

Notified Body
MedCert GmbH
Pilatuspool 2
20355 Hamburg
Identification number: 0482

hereby declare in own responsibility that the devices listed below are in compliance with the essential requirement of the following directive: Council directive 93/42/EEC amended by directive 2007/47/EC of 14th June 1993 concerning medical devices.

Reference Standards
Applicable standards are part of the technical documentation and can be viewed on request.

Single-Registration-Number
DE-MF-000005350

Validity
until 31.12.2028

Art.-No.	Product	Basic-UDI-DI	Classification according to to annex IX	Conformity Assessment Procedure
A-2396	OncoSet Y Link PES 0.2 µm CI		IIa	93/42/EWG - Anhang II
A-6416-4	RoweSpike I Chemo SV eco FI		Is	93/42/EWG - Anhang V
A-6407-7	RoweSpike I eco		Is	93/42/EWG - Anhang V
A-6442-8	RoweSpike II Chemo SV		Is	93/42/EWG - Anhang V
A-6415-5	RoweSpike I Chemo SV eco		Is	93/42/EWG - Anhang V
A-2607-6/115	QuiremSpheres® Delivery Set		Is	93/42/EWG - Anhang V

Parchim, 13.05.2024 Regulatory Affairs Manager

Vorlage_Konformitätserklärung / DoC-MDD-Klasse Is IIa

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Firmenstempel / Company Stamp