ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 001713 0008 Rev. 00

Manufacturer:

Q Core Medical Ltd.
29 Yad Haruzim St.
4250529 Netanya
ISRAEL

Authorized Representative:

MedNet GmbH
Borkstrasse 10, 48163 Muenster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 001713 0008 Rev. 00

Report No.: 713179583

Valid from: 2021-01-18
Valid until: 2026-01-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-01-18

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No. G10 001713 0008 Rev. 00

Classification:	IIb
Device Group:	Z12030301 - INFUSION PUMPS
Intended Purpose:	The Q Core Sapphire infusion pump is intended for controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, epidural medication, blood and blood products
Classification:	IIa
Device Group:	Z12030385 - INFUSION INSTRUMENTS - CONSUMABLES
Intended Purpose:	None
The validity of this certificate depends on conditions and/or is limited to the following:	None

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Action Name	User Name	Title	Signature Date
Send for Approval	Gabriel Zarbiv	VP Quality Assurance	15-Feb-2021 20:49 (GMT+2)
Start Approval	Judith Antler	VP QA/RA	16-Feb-2021 10:59 (GMT+2)