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 Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 111186 0002 Rev. 00

Manufacturer: **Q'Apel Medical, Inc.**
46708 Lakeview Blvd
Fremont CA 94538
USA

SRN Manufacturer: US-MF-00022759

Authorized Representative: MedEnvoy Global BV
Suite 123, Prinses Margrietplantsoen 33, 2595 AM The Hague,
THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. 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:G70 111186 0002 Rev. 00

Report No.: 72172090

Valid from: 2023-03-23
Valid until: 2028-03-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-03-23

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.15 16:29:23 EEST
Reason: MoldSign Signature
Location: Moldova

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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No. G70 111186 0002 Rev. 00

Classification:	Class III
Device Group:	C0104020103 - VASCULAR OCCLUSION CATHETERS
Basic UDI-DI:	0857545008NEUROACCESKD
Intended Purpose:	The 087 Balloon Guide Catheter System is intended to be placed in the internal carotid artery (ICA), facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the neurovasculature. The balloon provides temporary vascular occlusion during such procedures. The 087 Balloon Guide Catheter System is indicated for use in adult patients presented for treatment for acute ischemic stroke. The device is also indicated for use as a conduit for retrieval devices.
Device(s):	Walrus, 087 Balloon Guide Catheter System
The validity of this certificate depends on conditions and/or is limited to the following:	BG8087-090, BG8087-095, BG8087-100

Revision History:

Rev.	Dated	Report	Description
00	2023-03-23	72172090	Initial issuance

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