Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 024751 0027 Rev. 00

Manufacturer: **Quest Medical, Inc.**
One Allentown Parkway
Allen TX 75002-4211
USA

Product Category(ies): **Cardiovascular Surgical Devices, Fluid Delivery Devices, Manual Ophthalmic Surgical Devices, Intravenous Administration Sets, MPS Myocardial Protection System and Cardioplegia Catheters and Perfusion Sets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72147431

Valid from: 2020-01-15
Valid until: 2023-08-17

Date, 2020-01-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
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Facility(ies): Quest Medical, Inc.
One Allentown Parkway, Allen TX 75002-4211, USA

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