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ZLG-BS-244.10.08

TÜV SÜD 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 0025 Rev. 00

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

EC-Representative:
Emergo Europe B.V.
Prinsessegracht 20, 2514 AP The Hague, THE NETHERLANDS

Product Category(ies): **Cardiovascular Surgical Devices, Fluid Delivery Devices, Manual Ophthalmic Surgical Devices, Intravenous Administration Sets, MPS2 Myocardial Protection System, 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.: 72145794

Valid from: 2019-05-06
Valid until: 2023-08-17

Date, 2019-05-06

Stefan Preiß

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

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