CERTIFICAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認証書 ◆ CERTIFICATE ◆ CERTIFICAT

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 13 07 24751 015

Manufacturer:

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

EC-Representative:

M Devices Group
Riding Street, Marlborough
Southport, PR8 1EW
UNITED KINGDOM

Product Category(ies):

Cardiovascular Surgical Devices, Fluid Delivery Devices, Manual Ophthalmic Surgical Devices, Intravenous Administration Sets and MPS2 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.: DM1202822

Valid from: 2013-08-18
Valid until: 2018-08-17

Date, 2013-08-12

Hans-Heiner Junker

556576

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

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Facility(ies):

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