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 12 06 81184 001

Manufacturer:

VORTRAN Medical Technology 1, Inc
21 Goldenland CT, Suite 100
Sacramento CA 95834
USA

EC-Representative:

Katalytic Ltd.
Old School House
Merchant Taylors Close
Ashwell
Hertfordshire SG7 5LF
UNITED KINGDOM

Product Category(ies):

Single Patient Use Disposable Automatic Resuscitation Medical Devices

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.: DM1206142

Valid from: 2012-07-30
Valid until: 2017-07-29

512841

Date, 2012-08-01

Hans-Heiner Junker

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

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

No. G1 12 06 81184 001

Facility(ies):

VORTRAN Medical Technology 1, Inc
21 Goldenland CT, Suite 100, Sacramento CA 95834, USA