ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ 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 16 05 44789 013

Manufacturer:

ZOE Medical, Inc.
460 Boston Street
Topsfield MA 01983
USA

EC-Representative:

Estan AB
Ö. Stenby Prästgård
610 32 Vikbolandet
SWEDEN

Product Category(ies): **Patient Monitoring Systems**

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.: 72109180

Valid from: 2016-10-22
Valid until: 2021-10-21

Date, 2016-09-09

Stefan Preiß

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

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No. G1 16 05 44789 013

Facility(ies):

ZOE Medical, Inc.
460 Boston Street, Topsfield MA 01983, USA

Design Facility(ies):

ZOE Medical, Inc.
460 Boston Street, Topsfield MA 01983, USA

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