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 075182 0006 Rev. 00

Manufacturer:
PULSION Medical Systems SE
Hans-Riedl-Straße 17
85622 Feldkirchen
GERMANY

Facility(ies):
PULSION Medical Systems SE
Hans-Riedl-Straße 17, 85622 Feldkirchen, GERMANY

Product Category(ies):
Patient monitors including compatible modules, accessories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables

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.: 713153619

Valid from: 2019-05-17
Valid until: 2023-05-24

Date, 2019-05-17

Stefan Preiß

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

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