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 092547 0014 Rev. 01

Manufacturer:

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim
GERMANY

Facility(ies):

Roche Diabetes Care GmbH
Sandhofer Strasse 116, 68305 Mannheim, GERMANY

Product Category(ies):

Infusion/Injection Systems and Related Accessories
Blood Sampling Devices and Associated Lancets
Diabetes Management Medical Device Software

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.: 713157397

Valid from: 2019-05-01
Valid until: 2024-04-30

Date, 2019-04-10

Stefan Preiß

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany