Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 044934 0005 Rev. 00

Manufacturer:

Intensiv Medical Products IMPROMEDIFORM GmbH
Gielster Stück 11
58513 Lüdenscheid
GERMANY

Product Category(ies):

Class IIa, non-active medical devices: sterile administration sets and extension lines for intravenous infusion of medicines and other fluids to the body, sterile intravenous fluid containers (infusion bags), sterile administration sets for blood, blood derivatives or blood products (transfusion systems), and sterile pleural drainage sets (pleural punction sets), and sterile accessories for administration sets.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 713175325

Valid from: 2020-05-15
Valid until: 2023-12-17

Date, 2020-05-07

Christoph Dicks
Head of Certification/Notified Body

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

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

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