ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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

No. G2 105735 0004 Rev. 00

Manufacturer:

Poly Medicure Limited
Plot No.PA-010-018, PA-010-019
Mahindra World City (Jaipur) Ltd, Multi- Product SEZ
Jaipur, Rajasthan 302037
INDIA

Product Category(ies):

IV Cannula (Catheter with / without Safety Features). Infusion sets. Flow Regulators. Burette Infusion Set. Stop cocks with / without extension line. Extension line. Transfusion Set (BT Set). Yankaur Suction Set (Suction tube and/or Handle). Thoracic Drainage Catheter with/without Trocar. Infant Feeding tube. Mucus Extractor with / without bacterial filter. Suction catheter.Ryles tube, Levins tube

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 105735 0004 Rev. 00

Report No.: IND2020111

Valid from: 2021-04-30
Valid until: 2024-05-26

Date, 2021-04-30

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