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

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 080998 0017 Rev. 00

Manufacturer:

NIPRO INDIA CORPORATION PVT. LTD.
Plot No. E-1/1, Khandala PH-I Industrial
Area, Taluka-Khandala
District-Satara
412 802 Maharashtra
INDIA

Product Category(ies):

Sterile Dialyzers,
Sterile Hypodermic Syringes with Needles,
Sterile Arterial Venous Fistula Needles,
Sterile I.V Cannulae and Sterile Blood Tubing Sets

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.: IND2019114

Valid from: 2020-03-17
Valid until: 2024-05-26

Date, 2020-03-17

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