



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 080998 0014 Rev. 02

Holder of Certificate: **NIPRO INDIA CORPORATION PVT. LTD.**

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

Facility(ies): **NIPRO INDIA CORPORATION PVT. LTD.**

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

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Sterile Dialyzers, Sterile Hypodermic Syringes with and without Needles, Sterile Arterial Venous Fistula Needles, Sterile I.V. Cannulae, Sterile Blood Lines, Sterile Hypodermic Needles and Non-Sterile Bulk Cannulae Needles**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 080998 0014 Rev. 02

Report No.: 201530001527
Valid from: 2025-03-18
Valid until: 2028-03-17

Date, 2025-02-11

Christoph Dicks
Head of Certification/Notified Body