DAkkS
Deutsche Akkreditierungsstelle
D-ZM-11321-01-00

Digitally signed by Bolea Petru
Date: 2020.10.03 09:46:54 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD
Product Service

Certificate

No. Q5 043398 0289 Rev. 00

Holder of Certificate: **Nipro Corporation**
3-9-3, Honjo-Nishi, Kita-ku
Osaka 531-8510
JAPAN

Facility(ies): Nipro Corporation Odate Factory
8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5794 JAPAN

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Sterilization (EO, gamma and e-beam), Packaging, and Distribution of Sterile and Non-sterile Single Use Medical Products for Blood Sampling, Hemodialysis, Infusion, Injection, Perfusion, Plasmapheresis, Transfusion, Cardiovascular, Vascular, and ART (Assisted Reproductive Technology),**
Caps for the Application of Pharmaceutical Products, In-Vitro Diagnostic Kits for Biochemistry, Immunology and Genetics, Medical Grade Silicone

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: JNQ235033902

Valid from: 2018-09-01
Valid until: 2021-08-31

Date, 2018-08-28

Stefan Preiß

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

A4 / 07.17

TÜV®

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