Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-24110-20

Digitally signed by Bolea Petru
Date: 2020.10.03 09:45:24 EEST
Reason: MoldSign Signature
Location: Moldova

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 043398 0279 Rev. 01

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

Product Category(ies): **Packed Needles, PSV Sets, AVF Needles, Blood Lines, I.V. Catheters, Syringes with Needles, Blood Collection 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.: **JNQ235037648**

Valid from: **2019-10-31**
Valid until: **2024-05-26**

Date, **2019-10-31**

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

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

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 043398 0279 Rev. 01

Facility(ies):

Nipro Corporation
3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, JAPAN

-/-

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

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

TÜV®