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

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

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**Facility(ies):**

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

-/-


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