



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 0275 Rev. 01

Manufacturer:

Nipro Corporation

3-9-3, Honjo-Nishi, Kita-ku

Osaka 531-8510

JAPAN

Product Category(ies): Hemodialyzers, Hemofilters, Balloon Infusers, Endotoxin Filter, Huber Needles/Huber Needle Sets, Intravenous Catheters, Stopcocks, Biohole Kit, Hemodialysis Catheter, Hemoconcentrators, Hemodiafilters

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,

2019-11-04

Christoph Dicks

Head of Certification/Notified Body



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Facility(ies):

Nipro Corporation

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