ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Digitally signed by Bolea Petru
Date: 2020.10.03 09:45:42 EEST
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TÜV SÜD 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 18 01 43398 275

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

EC-Representative:
NIPRO MEDICAL EUROPE (Naamloze Vennootschap)
Blokhuisstraat 42,
2800 Mechelen,
BELGIUM

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.: **JNQ235032810**

Valid from: **2018-05-22**
Valid until: **2021-11-05**

Date, **2018-05-22**

Stefan Preiß

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

TÜV®

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Facility(ies):

Nipro Corporation
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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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