



EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 043398 0322 Rev. 00

Manufacturer:



NIPRO CORPORATION

3-26, Senriokashinmachi, Settsu
Osaka
566-8510, JAPAN

SRN Manufacturer - JP-MF-000026759

**Authorized
Representative:**

NIPRO MEDICAL EUROPE (Naamloze Vennootschap)
Blokhuisstraat 42, 2800 Mechelen, BELGIUM

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.

The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to

- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.

If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 043398 0322 Rev. 00

Report No.: JN200350007673
Preceding Certificate No.: G10 043398 0306 Rev. 01
G10 043398 0307 Rev. 03
G11 043398 0308 Rev. 02
Valid from: 2025-09-11
Valid until: 2027-10-12

Issue date: 2025-08-06

Christoph Dicks
Head of Certification/Notified
Body



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Classification:	Class IIa
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Classification:	Class IIb
Device Group:	F010601 - DIALYSERS - UFC < 18 ml/h/mmHg
Intended Purpose:	Intended to be used for medical conditions with markedly reduced kidney function resulting from chronic or acute renal failure. In cases of uremia, removes accumulations of water and uremic toxins.
Classification:	Class IIb
Device Group:	F010602 - DIALYSERS - UFC = 18 - 35 ml/h/mmHg
Intended Purpose:	Intended to be used for medical conditions with markedly reduced kidney function resulting from chronic or acute renal failure. In cases of uremia, removes accumulations of water and uremic toxins.
Classification:	Class IIb
Device Group:	F010603 - DIALYSERS - UFC > 35 ml/h/mmHg
Intended Purpose:	Intended to be used for medical conditions with markedly reduced kidney function resulting from chronic or acute renal failure. In cases of uremia, removes accumulations of water and uremic toxins.
Classification:	Class I
Device Group:	A01 - NEEDLES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A02 - SYRINGES
Device Properties:	MDS 1005 - Devices in sterile condition MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A07 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A99 - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	F90 - DIALYSIS DEVICES - VARIOUS
Device Properties:	MDS 1005 - Devices in sterile condition
The validity of this certificate depends on conditions and/or	-/-



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zfg.de
 BS-MDR-099



Product Service

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is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2025-09-11	JN200350007673	Administrative merge / transfer to new Certificate Type