EU Quality Management Certificate

This is to certify that the company

Nipro Pure Water GmbH

Werner-von-Siemens-Str. 2 - 6
76646 Bruchsal
Germany

SRN: DE-MF-00001 6554

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	301390 MDR2017Q
Certificate ID	1000183865
Effective date	2024-07-11
Expiry date	2028-08-31
Frankfurt am Main,	2024-07-11

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000016554
Certificate ID: 1000183865

Device categories and variants covered by this certificate:

Device category:	**MDA 0306 - Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemopheresis**
Product name:	RO Systems
Risk classification:	IIb
Basic-UDI-DI:	426069279NPW102FG
Intended purpose:	The RO Systems family is used for the central water treatment in dialysis. The device is a water purification system that uses reverse osmosis to remove microbiological, organic, and inorganic contaminants form the tap water. The purified water is used to dilute dialysis concentrate to form dialysate for dialysis machines/dialysers used in haemodialysis therapies.

Examinations and tests performed:
301390_A211388MED_01 dated 2023-08-09
301390_A211388MED_02 dated 2022-11-18
301390_A214877MED_01 dated 2024-06-14

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-09-01	170781900	Change of Certificate Template
02	2024-03-22	1000169581	Extension to product RO Systems