EC-Declaration of Conformity

Medical device class IIb, according to rule 9.3 Annex VIII of of the Medical Device Regulation (EU) 2017/745

Dialysis Water Treatment Systems

RO Systems

Including following variants:

Variant: Phoenix One; Variant: Phoenix One+,
Variant: Phoenix One+ FH; Variant: Phoenix One DS,
Variant: Phoenix One DS+; Variant: Phoenix One DS+ FH
Variant: RO Medical; Variant: RO Medical Basic

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 from the tap water. The purified water is used to dilute dialysis concentrate to form dialysate for dialysis machines/dialysers used in haemodialysis therapies.

Basic UDI-DI: 426069279NPW102FG

EMDN Code: Z12099007

The products above mentioned are conforming with the fundamental requirements:

REGULATION (EU) 2017/745 ANNEX IX CHAPTER I, III AND SECTION 4 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 April 2017 ON MEDICAL DEVICES

Digitally signed by Bolea Petru
Date: 2024.06.07 13:45:37 EEST
Reason: Moldsign signature
Location: Moldova

Further regulations:

Directive 2012/19/EU – (WEEE)
REGULATION (EC) No 1907/2006 – (REACH)
DIRECTIVE 2011/65/EU – (RoHS)
COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 – (Amendment of RoHS)

We, Nipro Pure Water GmbH, with address at Werner-von-Siemens-Str. 2-6, 76646 Bruchsal Germany, declare under our sole responsibility of the manufacturer that the goods mentioned above designated comply with the basic requirements of the regulation. This will be proved by the technical documentation and the full compliance with the relevant harmonized standards according to the documentation in the technical documentation (product file).

Single Registration Number (SRN): DE-MF-000016554

The requirements of the regulation are proven by the following certificates:

- The certificate of EU Technical Documentation with the registration No. 301390 MDR2017B, in compliance with the regulation (EU) 2017/745
- The certificate of EU Quality Management with the registration No. 301390 MDR2017Q, in compliance with the regulation (EU) 2017/745
- The certificate of Quality Management System with the Registration No. 301390MP2016, in compliance with EN ISO 13485:2016+AC:2017-07

The conformity assessment is based on a quality management system and on assessment of technical documentation according to Annex IX chapter I, III and section 4.

Notified body:
Identification number: 0297
DQS Medizinprodukte GmbH,
August-Schanz-Straße 21; 60433 Frankfurt a. M., Germany

Validity of declaration of conformity: January 2024 until December 2024

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Bruchsal, 02 January 2024

Heiko Sutter / PRRC & Technical Manager

Die wörtliche Übereinstimmung ~~vorstehen~~-
~~der~~ - umstehender - Abschrift - ~~Fotokopie~~ -
mit der mir vorliegenden Urschrift
- ..... ~~Ausfertigung~~ - ~~beglaubigten~~
~~Abschrift~~ - beglaubige ich.
Bruchsal, den 23.04.2024

Notar

THOMAS SCHABERT
NOTAR IN BRUCHSAL