EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Nipro Pure Water GmbH

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

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Water treatment systems for dialysis
Phoenix One, RO Medical and ROSI according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	301390 MR2
Certificate unique ID	170773747
Effective date	2021-01-24
Expiry date	2024-05-26
Frankfurt am Main	2021-01-24

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
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Device family	Device	Class
Phoenix One	Phoenix One	IIb
	Phoenix One+	
	Phoenix One+ FH	
	Phoenix One DS	
	Phoenix One DS+	
	Phoenix One DS+ FH	
RO Medical	RO Medical	IIb
	RO Medical Basic	
ROSI	ROSI	IIb