By Royal Charter

EU Quality Management System Certificate

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

MDR 739647 R000

Manufacturer: Nipro Renal Solutions Spain, S.L.U.

Address:
Pol. Ind. Tumsa, nave n°31
Mollerussa
Lleida
E-25230
Spain

Single Registration Number: ES-MF-000001481

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-03-18**

Current Issue Date: **2023-03-24**

Starting Validity Date: **2023-03-24**

Expiry Date: **2027-03-17**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Dialysis concentrates, Sodium Bicarbonate powder	For use in preparation of dialysis fluid used in hemodialysis and related therapies, for acute or chronic renal failure treatment
Dialysis concentrates, Acid solution	For use in preparation of dialysis fluid used in hemodialysis and related therapies, for acute or chronic renal failure treatment

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-03-18	3328216	Issued
Current	3869845	Supplemented – Addition of devices: Dialysis concentrates, Acid solution

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