By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 606979**

Issued To: **NIPRO RENAL SOLUTIONS SPAIN, S.R.L.**
Pol. Ind. Tumsa, nave nº 31
Mollerussa
Lleida
E-25230
Spain

Digitally signed by Bolea Petru
Date: 2021.04.19 12:48:07 EEST
Reason: MoldSign Signature
Location: Moldova

In respect of:

The design, development and manufacture of non-sterile liquid and dry concentrates for haemodialysis

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Albert Roossien, Regulatory Lead

First Issued: **2014-03-31** Date: **2019-02-06** Expiry Date: **2023-06-18**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2019-02-06**

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Date	Reference Number	Action
31 March 2014	8072088	First Issue. Transfer from another Notified Body
15 April 2015	8240124	Change of company Head Office address and correction of address stated on certificate.
20 June 2018	8891969	Certificate renewal. Removal of subcontractor Nipro Renal Solutions Spain, S.R.L., Plaza Manuel Bertran, 13 Piso 1º, Mollerussa, Lleida, E-25230, Spain.
Current	8197792	Traceable to NB 0086.

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