

EC Certificate - Full Quality Assurance System

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

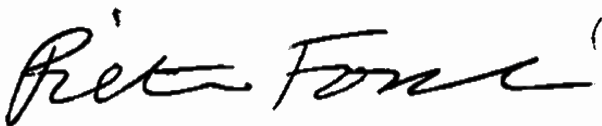
No. CE 606979
Issued To: **NIPRO RENAL SOLUTIONS SPAIN, S.R.L.**
Pol. Ind. Tumsa, nave nº 31
Mollerussa
Lleida
E-25230
Spain

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 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **31 March 2014**

Date: **15 April 2015**

Expiry Date: **18 June 2018**

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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.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

Nipro Renal Solutions Spain, S.R.L
Plaza Manuel Bertran, 13 Piso 1°
Mollerussa, Lleida
E-25230
Spain

**Purchasing
Sales**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 606979**
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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. |

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