By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 01931**

Issued To: **MTN Neubrandenburg GmbH**
Gustav Kirchhoff Str.2
17033 Neubrandenburg
Germany

In respect of:

The design, development and manufacture of dialysis concentrates, decalcification and disinfection fluids for dialysis machines.

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-05-29** Date: **2019-06-07** Expiry Date: **2023-05-28**

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Supplementary Information to CE 01931

Issued To:

MTN Neubrandenburg GmbH
Gustav Kirchhoff Str.2
17033 Neubrandenburg
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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 0102	Hemodialysis concentrates	Hemodialysis concentrates for acute and chronic renal failure, hyperhydration, intoxication, correction of acid/base metabolism and electrolyte status, adjustment of blood/plasma or body temperature
MD 0102 MD 0108	Disinfectants - dialysis	For heat disinfection, cleaning and decalcification of dialysis monitors

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01931**

Date: **2019-06-07**

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Date	Reference Number	Action
29 May 1998		Original issue.
11 November 2003		Reissue in new format, five-year renewal.
27 October 2004		Change to company name.
25 November 2004		Correction of company address.
01 January 2008	7146987	Management buy-out affecting company name with effect from 1st Jan 2008 (certificate issued in December 2007).
28 April 2008	7005781	Certificate renewal.
19 November 2008	7290695	The addition of 'Desinfection Fluids' to the scope of certification.
01 March 2011	7648916	Certificate change necessary because of an administrative error on customer reference 7005781 which was renewed for 3 years instead of the recommended 5 years.
28 May 2013	7943699	Certificate renewal.
28 May 2018	8923206	Certificate renewal. Scope reduction to remove decalcification and disinfection fluids for dialysis machines.
26 Februar 2019	7780184	Traceable to NB 0086.
Current	9754012	Addition of decalcification and disinfection fluids for dialysis to scope of certificate. Addition of product table.