

# EC Certificate - Full Quality Assurance System

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

**No.****CE 01931**

Issued To:

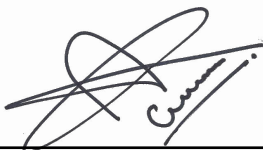
**MTN Neubrandenburg GmbH  
Gustav Kirchhoff Str.2  
17033 Neubrandenburg  
Germany**

In respect of:

**The design, development and manufacture of dialysis concentrates**

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: **1998-05-29**Date: **2019-02-26**Expiry Date: **2023-05-28**

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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.

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 01931**  
 Date: **2019-02-26**  
 Issued To: **MTN Neubrandenburg GmbH**  
**Gustav Kirchhoff Str.2**  
**17033 Neubrandenburg**  
**Germany**

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.
Current	7780184	Traceable to NB 0086.

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