By Royal Charter

EU Quality Management System Certificate

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

MDR 760035 R000

Manufacturer: MTN Neubrandenburg GmbH

Address:
Gustav-Kirchhoff-Straße 2
Neubrandenburg
17033
Germany

Single Registration Number: DE-MF-000007417

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: **2023-08-23**

Current Issue Date: **2023-08-23**

Starting Validity Date: **2023-08-23**

Expiry Date: **2028-08-22**

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Device Schedule: Class III and Class IIb devices

Class IIb, Non-Implantable	Intended purpose
Citric Acid 50%	Heat disinfection, cleaning and decalcification of haemodialysis monitors.
Powder set for preparation liquid hemodialysis concentration	The powder set is for the preparation of 100 I, 500 I or 1000 I acid dialysis concentrate and Citrasate bicarbonate haemodialysis concentrate (mixing ratio with water according to ISO 23500-3 1 +34 or 1 :44) using Herco or CK equipment. The ready to use solution is for extracorporeal bicarbonate dialysis. Use Acid Concentrate only in combination with bicarbonate hemodialysis concentrate (NaHCO3 8,4% or 6,6%) or bicarbonate cartridge in the given dilution; including on-line procedures, but only in combination with a hemodialysis monitor capable and intended for on-line treatments.
Liquid Hemodialysis Concentrate	For A-component, Citrasate and Bicarbonate concentrate: For extracorporeal bicarbonate dialysis. Use Acid Concentrate only in combination with bicarbonate hemodialysis concentrate or bicarbonate cartridge in the given dilution; including on-line procedures, but only in combination with a hemodialysis monitor capable and intended for on-line treatments. For acetate concentrate: For extracorporeal acetate dialysis

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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
Current	3560595	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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