

EU MDR Article 120 extension confirmation

Manufacturer Name ('Manufacturer')	Manufacturer Address	SRN Number
MTN Neubrandenburg GmbH	Gustav-Kirchhoff-Str. 2 17033 Neubrandenburg Germany	DE-MF-000007417

I/we declare that:

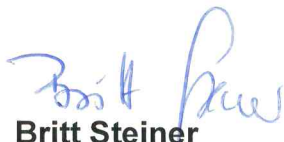
- the CE certificate(s) listed below were issued under the EU Medical Devices Directive (93/42/EEC) or under the EU Active Implantable Medical Devices Directive (90/385/EEC) on or after 25 May 2017 and were still valid on 26 May 2021 **AND**
- the conditions for extension of the validity of the CE certificate(s) (under the EU Medical Devices Regulation (2017/745) (EU MDR) Article 120) set out below have been met in relation to the CE certificates as listed in the table below

	CE Certificate number/s	Notified Body Number	Expiry date/s	Extended validity date for EU market
a) That, in the case of a certificate that expired before 20 March 2023 I/we/the manufacturer has a signed contract with a notified body that pre-dates the original expiry of the certificate	N/A	N/A	N/A	N/A
	CE Certificate number/s	Notified Body Number	Expiry date/s	Extended validity date for EU market
b) That, in the case of a certificate that expired before 20 March 2023 , no such contract (set out in (a) above) was signed before the date of certificate expiry, and the Manufacturer was granted in respect of the device: - a derogation from the conformity assessment procedures under EU	N/A	N/A	N/A	N/A

- MDR Article 59 OR a period of time to carry out conformity assessment in accordance with EU MDR Article 97				
	CE Certificate number/s	Notified Body Number	Expiry date/s	Extended validity date for EU market
c) The CE certificate(s) was due to expire on or after 20 March, and remains valid by virtue of EU MDR Article 120(2).	CE 01931	NB 2797	28.05.2023	31.12.2028

Devices covered by the extension
Liquid Haemodialysis Concentrate (MTNTF01)
Powder set for preparation Liquid Haemodialysis Concentrate (MTNTF02)
Citric acid 50 % (MTNTF03)

Signed by Manufacturer:


Britt Steiner



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Plant Manager

15.05.2023

Name of Signatory

Position of Signatory

Date