

## EC-Declaration of Conformity

We

MTN Neubrandenburg GmbH  
Gustav-Kirchhoff-Str. 2  
17033 Neubrandenburg, Germany

being the manufacturer within the European Union of the following dialysis treatment device(s):

### Disinfection and Decalcification Fluid for Dialysis machines

- Citric acid solution of 50 % acc. to Product Master V, enclosure product list

| Product code | Filling volume |
|--------------|----------------|
| 111100060851 | 6 l            |
| 111100050856 | 5 l            |

declare that the above mentioned device(s) is/are classified in class IIb, rule 15 and in conformity with the relevant provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC, concerning medical devices dated 14 June 1993, Annex I - Essential Requirements -, Annex IX - Classification criteria -, Annex XII - CE marking of conformity - , and our company has been subjected to the procedures laid down in Annex II, section 3.2 full quality assurance system - as certified in our certificate CE 01931 - of the above mentioned directive under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands B.V, and carrying the Notified Body Number 2797.

The maintained traceability ensures all regulatory requirements under the Directives remain valid and assessed. MTN will execute labelling transition within 12 months.

This device does not incorporate, as an integral part, a substance as referred to the above mentioned Directive Annex I section 7.4.

This declaration covered all products of the above mentioned types.

Neubrandenburg, Germany

Date: 28.01.2020



Britt Steiner  
Quality Assurance Manager