

# 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):

## Acid Concentrate for Bicarbonate Dialysis – Citrasate® acc. to Product MasterVI

Product code	Filling volume
41000060011	6 l
41100060011	6 l
41300060011	6 l
41500100011	6 l
46000050011	6 l
46100050011	5 l
46300050011	5 l
46500050011	5 l

declare that the above mentioned device(s) is/are classified in class IIb, rule 3 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 was originally under the supervision of the British Standards Institution, a Notified Body authorized by the United Kingdom Competent Authority, and carrying the Notified Body Number 0086 and has migrated to BSI Group The Netherlands B.V., Notified Body Number 2797.


The maintained traceability ensures all regulatory requirements under the Directives remain valid and assessed.

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

This declaration covered all products of the above mentioned types.

Neubrandenburg, Germany

Date: 2020-01-28

  
Britt Steiner  
Quality Assurance Manager