FRESENIUS MEDICAL CARE

EC DECLARATION OF CONFORMITY

No. 08/03/01/001

Fresenius Medical Care AG & Co. KGaA

(Manufacturer)

61346 Bad Homburg - Germany

(Address)

declares under his sole responsibility that the product

Sodium Citrate 4% w/v

Solution for regional anticoagulation

meets the applicable provisions of the European Medical Device Directive 93/42/EEC, its relevant national transpositions and the relevant standards as specified in the technical file.

Product group:	**Citrate Solution**
Risk class: (according to annex IX MDD 93/42/EEC)	**IIb**
Conformity assessment procedure:	**Annex V**
Notified body:	**TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München - Germany**
Notified body no.:	**0123**
First batch/Serial number:	**A3LA221**

Bad Homburg, 05/03/19
Place and date

Joseph P. Winslow
Joe Winslow
Product Center Responsible Person

Bad Homburg, 05/03/19
Place and date

Kümmerle
W. Kümmerle
QREM Responsible Person

This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.

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Versions:

Product Code	Product Name
F00008029	Sodium Citrate 4% w/v
F00008103	Sodium Citrate 4% w/v
F00008104	Sodium Citrate 4% w/v
F00008105	Sodium Citrate 4% w/v

Accessories:

(according to the European Medical Device Directive 93/42/EEC)

Product Code	Product Name
Various products for Ci-Ca CVVHD or Ci-Ca-CVVHDF	Various products for Ci-Ca CVVHD or Ci-Ca-CVVHDF

Additional equipment:

Product Code	Product Name
n.a.	n.a.

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