

EC Declaration of Conformity

Legal Entity: Terumo BCT, Inc.

Address of Legal Entity: 10811 West Collins Avenue
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Name of the Device Concerned: Anticoagulant Citrate Dextrose Solution Ph Eur (ACD) Solution A (ACDA)

Device Class and Classification Rule: Classification of the Anticoagulant Citrate Dextrose Solution Ph Eur (ACD) Solution A (ACDA) is based on the classification rules set out in Annex IX of the Directive. ACDA is Class IIb based on Rule 3. No rule in the directive would classify any component as Class III. This device does not incorporate, as an integral part, a medicinal product as referred to in the above-mentioned directive, Annex I, Section 7.4.

GMDN Code: Blood Storage Solution, Anticoagulant [46812]

Conformity Assessment Procedure: Medical Device Directive (93/42/EEC as amended. Annex II, Section 3.2

Address of Notified Body: BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam

Notified Body Number: 2797

We hereby declare that the devices on this page and page 2 of this declaration comply with the European Council Directive 93/42/EEC and its amendments concerning medical devices.

None of the devices identified in this declaration contain medicinal substances of animal origin.



Karen Lowitz
Manager Regulatory Affairs

2019-04-15

Date (yyyy-mm-dd)

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Appendix

Catalog Number	Description	Classification and Rule
40801	Anticoagulant Citrate Dextrose Solution, ACD-A 750mL EMEA & Nordic	Class IIb per rule 3
40802	Anticoagulant Citrate Dextrose Solution, ACD-A 750mL Australia	Class IIb per rule 3
40804	Anticoagulant Citrate Dextrose Solution, ACD-A 500mL EMEA & Nordic	Class IIb per rule 3
40808	Anticoagulant Citrate Dextrose Solution, ACD-A 750mL EMEA	Class IIb per rule 3
40809	Anticoagulant Citrate Dextrose Solution, ACD-A 750mL Australia	Class IIb per rule 3
40814	Anticoagulant Citrate Dextrose Solution, ACD-A 500mL EMEA	Class IIb per rule 3
40818	Anticoagulant Citrate Dextrose Solution, ACD-A 750mL EMEA	Class IIb per rule 3