TERUMOBCT

EC Declaration of Conformity

Legal Entity:	Terumo BCT, Inc.
Address of Legal Entity:	10811 West Collins Avenue Lakewood Colorado, 80215 USA
Authorized Representative established in the Community	Terumo BCT Europe NV Ikaroslaan 41 1930 Zaventem Belgium Tel: +32.2.715.05.90 Fax: +32.2.721.07.70
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 Kitemark Court Davey Avenue Knowlhill Milton Keynes MK5 8PP United Kingdom
Notified Body Number:	0086

Digitally signed by Apostol Eduard
Date: 2021.02.10 09:10:01 EET
Reason: MoldSign Signature
Location: Moldova

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.

Mark Holmes
Vice President

12 Aug 2013
Date (day/month/year)

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Appendix
Equipment Models

Catalog Number	Product Name	Classification 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

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