

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: Device Class and Classification Rule:	Spectra Optia Apheresis System (consisting of Equipment and Disposables) Classification of the Spectra Optia Apheresis System (consisting of Equipment and Disposables) is based on the classification rules set out in Annex IX of the Directive. The Equipment is classed as IIb based on rule 11. The Disposable Exchange sets and the Single Needle Connector Set used with the Spectra Optia are classed as IIa based on rules 3 and the Collection; IDL; Platelet, Plasma; and BMP sets are classed as IIb based on rule 18. Section 2.2 of Annex IX of the Directive requires devices used in combination with another device to be classified separately to each of the devices. The Accessory Waste Bag is Class IS based on Rule 1. 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:	Apheresis Unit [16405] Blood Collection Tubing Set [44903]
Conformity Assessment Procedure:	Medical Device Directive 93/42/EEC as amended. Annex II, Section 3.2
Conformity Assessment Certificates:	CE 00326 Date: 2020-02-01 Expiry Date:2024-05-26
Address of Notified Body:	BSI Group The Netherlands B.V. John M. Keynesplein 9 1066 EP Amsterdam
Notified Body Number:	2797

Terumo BCT, Inc.

10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.

Europe, Middle East and Africa
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: +32.2.715.0590
Fax: +32.2.721.0770

Terumo BCT Asia Pte. Ltd.

89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261
Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A

La Pampa 1517-12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.

Tokyo Opera City Tower 49F,
3-20-2, Nishi-Shinjuku,
Shinjuku-ku, Tokyo 163-1450,
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

We hereby declare that the devices on pages 1 through 3 of this declaration comply with the European Council Directive 93/42/EEC and its amendments concerning medical devices and the Machinery Directive, 2006/42/EC.

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



Nicholas Tabrizi
Sr. Manager, Regulatory Affairs

15FEB2022

Date

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Appendix Equipment Catalogue Numbers

Equipment Catalog Numbers	Product Name	Classification Rule
61000	Spectra Optia System	Class IIb, Rule 11
703162-015	Spectra Optia, Version 11.3 Software	Class IIb, Rule 11
705310-000	Spectra Optia, Version 12.0 Software	Class IIb, Rule 11

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Appendix
Disposable Catalogue Numbers**

Disposable Catalogue Number	Product Name	Classification Rule
10110	Spectra Optia Collection Set	Class IIb, Rule 18
10120	Spectra Optia Collection Set	Class IIb, Rule 18
10123	Spectra Optia Collection Set (France)	Class IIb, Rule 18
10125	Spectra Optia Collection Set (Brazil)	Class IIb, Rule 18
12120	Spectra Optia Collection Set	Class IIb, Rule 18
12123	Spectra Optia Collection Set (France)	Class IIb, Rule 18
10220	Spectra Optia Exchange Set	Class IIa, Rule 3
10223	Spectra Optia Exchange Set (France)	Class IIa, Rule 3
10225	Spectra Optia Exchange Set (Brazil)	Class IIa, Rule 3
12220	Spectra Optia Exchange Set	Class IIa, Rule 3
12223	Spectra Optia Exchange Set (France)	Class IIa, Rule 3
10300	Spectra Optia IDL Set	Class IIb, Rule 18
10310	Spectra Optia IDL Set	Class IIb, Rule 18
10313	Spectra Optia IDL Set (France)	Class IIb, Rule 18
10315	Spectra Optia IDL Set (Brazil)	Class IIb, Rule 18
12320	Spectra Optia IDL Set	Class IIb, Rule 18
12323	Spectra Optia IDL Set (France)	Class IIb, Rule 18
10400	Spectra Optia Platelet, Plasma Set	Class IIb, Rule 18
10405	Spectra Optia Platelet, Plasma Set (Brazil)	Class IIb, Rule 18
12400	Spectra Optia® LRS® Platelet, Plasma Set	Class IIb, Rule 18

11300	Spectra Optia BMP Accessory Set	Class IIb, Rule 18
11303	Spectra Optia BMP Set (France)	Class IIb, Rule 18
11305	Spectra Optia BMP Set (Brazil)	Class IIb, Rule 18
11220	Spectra Optia Single-Needle Connector	Class IIa, Rule 3
11221	Anticoagulant Connection Adapter	Class IIa, Rule 2
70040	Accessory Waste Bag	Class I S, Rule 1
70060	Accessory Plasma Storage Set	Class IIb, Rule 18