

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: Terumo – Platelet Additive Solution + (T-PAS+)

Device Class and Classification Rule: Classification of the Terumo – Platelet Additive Solution + (T-PAS+) is based on the classification rules set out in Annex IX of the Directive. T-PAS+ 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 [46668]

Conformity Assessment Procedure: Medical Device Directive 93/42/EEC as amended. Annex II, Section 3.2 excluding (4)

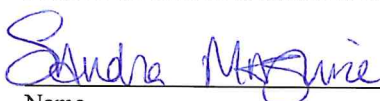
Conformity Assessment Certificates: CE 00326
Date: 01-Feb-2020
Expiry Date: 26-May-2024

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

Notified Body Number: 2797

We hereby declare that the devices on pages 1 and 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 or materials of animal origin.



Name
Manager of Regulatory Affairs

2021-03-18
Date (yyyy-mm-dd)

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

EC Declaration of Conformity

Applicable Products

Catalog Number	Product Name	Classification Rule and Class
40840	Terumo Platelet Additive Solution + (T-PAS+) 200mL (polypropylene bag)	Class IIb per rule 3
40841	Terumo Platelet Additive Solution + (T-PAS+) 250mL (polypropylene bag)	Class IIb per rule 3
40842	Terumo Platelet Additive Solution + (T-PAS+) 300mL (polypropylene bag)	Class IIb per rule 3
40843	Terumo Platelet Additive Solution + (T-PAS+) 500mL (polypropylene bag)	Class IIb per rule 3
40844	Terumo Platelet Additive Solution + (T-PAS+) 220mL (polypropylene bag)	Class IIb per rule 3
40845	Terumo Platelet Additive Solution + (T-PAS+) 280mL (polypropylene bag)	Class IIb per rule 3
40846	Terumo Platelet Additive Solution + (T-PAS+) 500mL (polypropylene bag)	Class IIb per rule 3
40851	Terumo Platelet Additive Solution + (T-PAS+) 200mL (polyolefin bag (non-DEHP))	Class IIb per rule 3
40852	Terumo Platelet Additive Solution + (T-PAS+) 220mL (polyolefin bag (non-DEHP))	Class IIb per rule 3
40853	Terumo Platelet Additive Solution + (T-PAS+) 250mL (polyolefin bag (non-DEHP))	Class IIb per rule 3
40854	Terumo Platelet Additive Solution + (T-PAS+) 280mL (polyolefin bag (non-DEHP))	Class IIb per rule 3
40855	Terumo Platelet Additive Solution + (T-PAS+) 300mL (polyolefin bag (non-DEHP))	Class IIb per rule 3
40856	Terumo Platelet Additive Solution + (T-PAS+) 500mL (polyolefin bag (non-DEHP))	Class IIb per rule 3

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