

EC Declaration of Conformity

Legal Entity: Terumo BCT, Inc.

Address of Legal Entity: 10811 West Collins Avenue
Lakewood
Colorado, 8015
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: Trima Accel® Automated Blood Collection System (consisting of equipment and disposables)

Device Class and Classification Rule: Classification of the Trima Accel Automated Blood Collection 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 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. 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: Aphaeresis System [16405]
Apheresis System Tubing Set [47572]
Blood Collection Tubing Set [44903]

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 pages 1 to 4 of this declaration comply with the European Council Directive 93/42/EEC and its amendments concerning medical devices.


Isabel McGann
Director of Regulatory Affairs, Americas


Date (YYYY-MM-DD)

EC Declaration of Conformity

Appendix Equipment Models

Catalog Number	Product Name	Classification Rule
81000	Trima Accel® Automated Blood Collection System	Class IIb, Rule 11
81011	Trima Accel® Automated Blood Collection System, China	Class IIb, Rule 11
704307-000	Trima Accel® Automated Blood Collection System, Version 5.1	Class IIb, Rule 11
704415-000	Trima Accel® Automated Blood Collection System, Version 6.0	Class IIb, Rule 11
704461-001	Trima Accel® Automated Blood Collection System, Version 6.2	Class IIb, Rule 11
773899-333 773899-330	Trima Accel® Automated Blood Collection System, Version 7.0	Class IIb, Rule 11
777110-037	Trima® Seal Safe System	Class IIb, Rule 11

EC Declaration of Conformity

Appendix Disposable Models

Disposable Sets Catalog Number	Product Name	Classification Rule
11221	Anticoagulant Connection Adapter	Class IIa, Rule 2
70030	Accessory Platelet Storage Set	Class IIb, Rule 18
70051	Blood Component Sampling Set	Class IIb, Rule 18
70060	Accessory Plasma Storage Set	Class IIb, Rule 18
80300	Trima Accel® LRS® Platelet, Plasma Set	Class IIb, Rule 18
80301	Trima Accel® LRS® Platelet, Plasma Set	Class IIb, Rule 18
80310	Trima Accel® Platelet + Sampler + Auto PAS, MultiPlasma Set	Class IIb, Rule 18
80330	Trima Accel® LRS Platelet, Plasma Set	Class IIb, Rule 18
80340	Trima Accel® LRS Platelet + 35 mL Sampler, Multi Plasma, RBC Set	Class IIb, Rule 18
80350	Trima Accel® Platelet, Plasma, Auto RBC Set	Class IIb, Rule 18
80356	Trima Accel® Platelet, Plasma, Auto RBC Set	Class IIb, Rule 18
80360	Trima Accel® Platelet + Sampler, Plasma, Auto RBC Set	Class IIb, Rule 18
80366	Trima Accel® Platelet + Sampler, Plasma, Auto RBC Set	Class IIb, Rule 18
80370	Trima Accel® Platelet + Sampler + Auto PAS, MultiPlasma, RBC Set	Class IIb, Rule 18
80400	Trima Accel® LRS® Platelet, Plasma, RBC Set	Class IIb, Rule 18
80406	Trima Accel® LRS® Platelet, Plasma, RBC Set	Class IIb, Rule 18
80410	Trima Accel® LRS® Platelet, Plasma, RBC + Auto PAS Set	Class IIb, Rule 18
80420	Trima Accel® Platelet + Sampler, Plasma, RBC + Auto PAS Set	Class IIb, Rule 18
80440	Trima Accel® Platelet + Sampler, Plasma, RBC Set	Class IIb, Rule 18
80446	Trima Accel® Platelet + Sampler, Plasma, RBC Set	Class IIb, Rule 18
80450	Trima Accel® LRS® Platelet, Plasma, RBC + TLR Filter Set	Class IIb, Rule 18
80470	Trima Accel® Platelet + Auto PAS, Plasma, Auto RBC Set	Class IIb, Rule 18
80480	Trima Accel® LRS® Platelet, Plasma, RBC + TLR Filter + Auto PAS Set	Class IIb, Rule 18
80483	Trima Accel® Platelet + Plt Filter + Auto PAS, Plasma, RBC + TLR Filter Set	Class IIb, Rule 18
80490	Trima Accel® PPC + Sampler, Plasma, RBC Set	Class IIb, Rule 18
80491	Trima Accel® PPC + Sampler, Plasma, RBC Set	Class IIb, Rule 18
80500	Trima Accel® RBC, Plasma Set	Class IIb, Rule 18
80520	Trima Accel® Auto RBC, Plasma Set	Class IIb, Rule 18
80550	Trima Accel® RBC + TLR Filter, Plasma Set	Class IIb, Rule 18
80700	Trima Accel® MultiPlasma Set	Class IIb, Rule 18
82300	Trima Accel® LRS® Platelet, Plasma Set	Class IIb, Rule 18
82310	Trima Accel® LRS Platelet + Sampler + Auto PAS, MultiPlasma Set	Class IIb, Rule 18
82321	Trima Accel® LRS Platelet + Sampler + Auto PAS Set	Class IIb, Rule 18
82330	Trima Accel® LRS Platelet, Plasma Set	Class IIb, Rule 18
82383	Trima Accel® LRS® Platelet + Plt Filter + Auto PAS, Plasma Set	Class IIb, Rule 18
82400	Trima Accel® LRS® Platelet, Plasma, RBC Set	Class IIb, Rule 18
82406	Trima Accel® LRS® Platelet, Plasma, RBC Set	Class IIb, Rule 18
82408	Trima Accel® LRS Platelet + 35 mL Sampler, MultiPlasma, RBC Set	Class IIb, Rule 18
82410	Trima Accel® LRS Platelet + Auto PAS, Plasma, RBC Set	Class IIb, Rule 18
82416	Trima Accel® LRS Platelet + 35 mL Sampler, MultiPlasma, RBC Set	Class IIb, Rule 18
82420	Trima Accel® LRS Platelet + Sampler + Auto PAS, Plasma, RBC Set	Class IIb, Rule 18
82440	Trima Accel® LRS Platelet + Sampler, Plasma, RBC Set	Class IIb, Rule 18

Disposable Sets Catalog Number	Product Name	Classification Rule
82446	Trima Accel® LRS Platelet + Sampler, Plasma, RBC Set	Class IIb, Rule 18
82460	Trima Accel® LRS Platelet + Sampler + Auto PAS, MultiPlasma, RBC Set	Class IIb, Rule 18
82470	Trima Accel® LRS Platelet + Auto PAS, Plasma, Auto RBC Set	Class IIb, Rule 18
82483	Trima Accel® LRS Platelet + Plt Filter + Auto PAS, Plasma, RBC + TLR Filter Set	Class IIb, Rule 18
82500	Trima Accel® RBC, Plasma Set	Class IIb, Rule 18
82520	Trima Accel® Auto RBC, Plasma Set	Class IIb, Rule 18
82616	Trima Accel® LRS Platelet + 35 mL Sampler, Plasma, Auto RBC Set	Class IIb, Rule 18
82650	Trima Accel® LRS Platelet, Plasma, Auto RBC Set	Class IIb, Rule 18
82656	Trima Accel® LRS Platelet, Plasma, Auto RBC Set	Class IIb, Rule 18
82660	Trima Accel® LRS Platelet + Sampler, Plasma, Auto RBC Set	Class IIb, Rule 18
82666	Trima Accel® LRS Platelet + Sampler, Plasma, Auto RBC Set	Class IIb, Rule 18
82668	Trima Accel® LRS Platelet + 35 mL Sampler, Plasma, Auto RBC Set	Class IIb, Rule 18
82700	Trima Accel® MultiPlasma Set	Class IIb, Rule 18