TERUMOBCT

CERTIFICATE OF COMPLIANCE

Product	ACCEL PLATELET PLASMA SET		
Catalog Number	80337	Lot Number	01A0203
Manufacture Date	2017/01/01	Expiry Date	2019/01/01

The above product has been manufactured according to U.S. FDA Quality System Regulations and ISO 13485:2003 and complies with the relevant requirements of the European Medical Device Directive 93/42/EEC as amended.

The following product attributes are certified for this product lot:

Item	Standard	Pass
External Appearance	The product has been visually inspected and meets the requirements of the Device Master Record.	Y
Packaging	The container in which this product is directly maintained, or the package which directly covers this product shall adequately protect the product.	Y
Labelling	All labelling conforms to the specifications listed in the Device Master Record.	Y
Cleanroom Assembly	This product has been assembled with component traceability and lot control in an ISO Class 8 cleanroom per ISO 14644-1: 1999 *Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness.*	Y
Performance	A sample of this lot has been inspected and has passed the requirements of visual and simulated use tests.	Y
Biocompatibility and Physical Chemical Testing	The fluid pathway materials of this product have been tested and passed the preclincal evaluation of medical device testing as defined by the ISO 10993-1: 2009 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system.* The materials have been evaluated and/or tested for cytotoxicity (L929 Fluid Elution Test), hemocompatibility (hemolysis), systemic toxicity-acute (USP or ISO), intracutaneous reactivity(USP or ISO), genotoxicity (mutation assay), sensitization (Kligman maximization test – modified), and subchronic toxicity [14 Day Repeat Dose Intravenous Toxicity study (subchronic)-ISO), if applicable]. Physicochemical testing requirements have also met the appropriate United States Pharmacopoeia (USP), European Pharmacopoeia (EP), German DIN 58352-3, or Italian Pharmacopoeia IX (IP) tests. In addition, the storage bags for blood components are made of PVC plasticized with butyrl trihexyl citrate (Citroflex B-6) or DEHP, and meet the physico-chemical and biological testing requirements of EP 3.1.1., 3.2.2., and 3.2.4. and/or ISO 3826-1.	Y
Pyrogenicity	The Pyrogenicity of the disposables fluid pathway has been bacterial endotoxin tested and meets the endotoxin criteria in accordance with established manufacturing operating procedures. These procedures are based on and in compliance with manufacturer recommendations, USP<85> *Bacterial Endotoxins Test*, AAMI ST72:2011 *Bacterial Endotoxins – Test methods, routine monitoring*, and alternatives to batch testing and/or FDA LAL testing guidelines appropriate for medical devices (FDA *Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers,* June 2012). The Endotoxin specification is ≤ 200 endotoxin units (EU) per test or an average of 20.0 EU/device for 10 pooled devices.	Y
Sterility	This product has been processed with ETO to achieve a 10^{-6} sterility assurance level in accordance with ISO 11135-1:2007 *Sterilization of health care products – Ethylene Oxide- Part 1: Requirements for development and routine control of a sterilization process for medical devices.*	Y
EtO Residual	This product has been validated to achieve less than 6mg EtO, meeting the requirements of ISO 10993-7:2008 *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals* prior to release and less then 1ppm in the collect bag at time of use.	Y
Final Release	This product has been released using procedures that comply with the FDA Quality System Regulations and ISO 13485:2003 *Medical devices – Quality management systems – Requirements for regulatory purpose.*	Y
Lot Documentation	Stored for 7 years	Y

We affirm the above to be accurate and based on the tests we have executed.

Jan Hudock, Quality Assurance Representative

Disposables Quality Manager

Title

2017/01/20

Product Release Date

Terumo BCT, Inc.
10811 W. Collins Avenue
Lakewood, Colorado 80215 USA
www.TerumoBCT.com

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