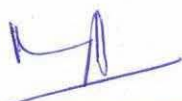


EU Declaration of Conformity

Manufacturer Name: TERUMO PENPOL Private Limited
Manufacturer Address: Puliyaakonam
Thiruvananthapuram – 695 573
India
Manufacturer Site Name: TERUMO PENPOL Private Limited
Manufacturer Site Address: Medical Systems Group, T.C.27/373, Andoor Buildings,
General Hospital Road, Thiruvananthapuram, Kerala - 695 035, India
Authorized Representative Name: Terumo BCT Europe NV
Authorized Representative Address: Ikaroslaan 41
1930 Zaventem
Belgium
Tel: +32.2.715.05.90
Fax: +32.2.721.07.70
Basic UDI-DI Number: 89040093PlateletIncubatrWV
Device Name: Platelet Incubator
Product code: See attached list
Intended Purpose: The Platelet Incubator TC200 is designed to store platelet concentrates in controlled temperatures. Platelet Incubator TC200 with Platelet Agitator increases platelet viability, post transfusion recovery and preservation of platelet morphology.
Classification: Class I based on rule 1 and 13 (according to Annex VIII of the Medical Device Regulation – EU Regulation 2017/745).
Conformity Assessment Route: Medical Device Regulation – EU Regulation 2017/745 Annex II, III and IV
GMDN Code: 62158, Platelet Incubator.
CND Code: Z121799, Blood Transfusion Instruments – Others

TERUMO PENPOL Private Limited under its sole responsibility hereby declare that the device on page 2 of this declaration complies with the European Council Regulation 2017/745 of 5 April 2017, concerning medical devices, and any other relevant EU legislation applicable to the device, including Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility, concerning Electromagnetic Compatibility and the Directives (EU) 2017/2102 of the European Parliament and the Council of 15 November 2017, amending Directive 2011/65/EU (RoHS) “On the Restriction of the use of certain hazardous substances in electrical and electronic equipment”.

This declaration is signed on behalf of the manufacturer, TERUMO PENPOL Private Limited and is issued at the address of the manufacturer.



Manoj Appukuttan
Vice-President – Innovation & Development, India

2020-02-06
Date (yyyy-mm-dd)

EC Declaration of Conformity

Device Models

Catalog Number	Product Name	Classification Rule
TC200	Platelet Incubator	1 and 13