

MANUFACTURER: TERUMO PENPOL Private Limited
Puliyarakonam,
Thiruvananthapuram, India - 695 573.

EUROPEAN REPRESENTATIVE: TERUMO BCT EUROPE N.V.
NAME AND ADDRESS: Ikaroslaan 41, 1930 Zaventem,
Belgium.

PRODUCTS: The sterile blood bags with / without Anticoagulant/
Preservative solution
The sterile blood bags with /without Anticoagulant /
Preservative solution with satellite bags
The sterile blood bags with leukocyte filter and
anticoagulant / Preservative solution with satellite bags
The sterile blood sampling bags (Blood bag accessory for
sampling purpose)

CLASSIFICATION: Class **II b** under the rule 18 of Annexure IX of Council
Directive 93/42/EEC

CONFORMITY ASSESSMENT
ROUTE: paragraph 3(a) of the Article II in the MDD, that is,
Annex II (except for section 4).

We herewith declare that the above mentioned products meet the provisions of the council directive
93/42/EEC amended by 2007/47/EC for medical devices. All supporting documentations retained
under the premises of the manufacturer.

STANDARDS APPLIED: ISO 3826-1:2013, ISO 3826-2:2008, ISO 3826-3:2006 EN 556-1:2001,
ISO 17665-1:2006/EN ISO 17665-1:2006, EN ISO 13485:2016, EN ISO
14971:2012, ISO 10993-1:2009/ EN ISO 10993-1:2009, EN 15986:2011
ISO 11607-1:2006/ EN ISO 11607-1:2009, EN 1041:2008 +A1:2013, ISO
15223-1:2012/ EN ISO 15223-1:2016, ISO 14644-1:2015, IEC 62366-1-
2015 , ISO 14155-1:2011, ISO 1135-4:2012, EN 15986:2011

NOTIFIED BODY: Societe Generale de Surveillance (SGS).
SGS Belgium NV, Notified Body 1639,
SGS House Noorderlaan 87 2030
Antwerp Belgium

(EC) CERTIFICATE(S): IN19/818843705

START OF CE-MARKING: 08th August 2000
PLACE, DATE OF ISSUE: Thiruvananthapuram, India, 10th November 2023.

SIGNATURE:  _____

NAME: A.MANOJ
POSITION: VICE PRESIDENT GLOBAL PRODUCT DEVELOPMENT & ENGINEERING.

