

EC Certificate Full Quality Assurance System: Certificate IN19/818843705

The management system of

Terumo Penpol Private Limited

Registered Office:
I-2, Jawahar Nagar, Kowdiar PO,
Thiruvananthapuram - 695 003, India

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 08 August 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 08 August 2000
and first certified by SGS Belgium NV since 16 December 2019.

This is a multi-site certification.
Additional site details are listed on subsequent page

Certification is based on reports numbered IN/CHE 235593

Authorised by

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Certificate IN19/818843705 continued

Terumo Penpol Private Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

**Sterile Blood bags with and without anticoagulants
and with and without in-line filter**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

Factory: Puliarakonam, Thiruvananthapuram - 695 573, India

**Warehouse: Bldg.No.770/SDF-3/GF/1, Thumba, St. Xaviers College P.O,
Thiruvananthapuram - 695 586, India**