Terumo Penpol Private Limited
Puliyarakonam
Thiruvananthapuram
Kerala – 695 573
India

05 November 2024

**Notified Body Confirmation Letter**

**Reference: EU2023-607/992258**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Terumo Penpol Private Limited
Puliyarakonam
Thiruvananthapuram
Kerala – 695 573
India
SRN Number: IN-MF-000001071

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive

93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Devon Hall

Digitally signed by Devon Hall
Date: 2024.11.05 06:52:00 -07'00'

Devon Hall

BSI Scheme Manager

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| PB-1CD156M5S Blood Bag CPDA-1 150 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD256M5S Blood Bag CPDA-1 250 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD256M8B Blood Bag CPDA-1 250 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456M0Y Blood Bag CPDA-1 450 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456M0Z Blood Bag CPDA-1 450 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456M8Y Blood Bag CPDA-1 450 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD356M0Y Blood Bag CPDA-1 350 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD356M8Y Blood Bag CPDA-1 350 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD456M0Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD456M8Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3CD356M8Y Blood Bag CPDA-1 350 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3CD456M0Y Blood Bag CPDA-1 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3CD456M8Y | Class III | N/A | SGS Belgium NV - IN19/818843705 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| Blood Bag CPDA-1 450 ml Triple Bag | | | |
| PB-3AG456M0Y Blood Bag CPD SAG-M 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3AG456M8Y Blood Bag CPD SAG-M 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3BG456M0Y Blood Bag CPD SAG-M TAB 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4AG456M0X Blood Bag CPD SAG-M 450 ml Quadruple Bag Buffy | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4AG456M0Y Blood Bag CPD SAG-M 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4BG456M0Y Blood Bag CPD SAG-M TAB 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3BG456A0Y Blood Bag CPD SAG-M TAB 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4BG456A0Y Blood Bag CPD SAG-M TAB 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD256E8B Blood Bag CPDA-1 250 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD356E8Y Blood Bag CPDA-1 350 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| PB-3AG456E0Y Blood Bag CPD SAG-M 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3AO356E0Y Blood Bag CPD SAG-M-2 350 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4AG456E0Y Blood Bag CPD SAG-M 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4AO456E0X Blood Bag CPD SAG-M-2(OPTISOL) 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4BO456E0Y Blood Bag CPD SAG-M-2 TAB 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456I9Z Blood Bag CPDA-1 450 ml Single Bag(Autologous Bag) | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456L8Y Blood Bag CPDA-1 450 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD456L8Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3CD456L8Y Blood Bag CPDA-1 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4BG456L0Y Blood Bag CPD SAG-M TAB 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456Q2Y | Class III | N/A | SGS Belgium NV - IN19/818843705 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| Blood Bag CPDA-1 450 ml Single Bag | | | |
| PB-2CD456Q0Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3CD456Q0Y Blood Bag CPDA-1 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3AG456Q0Y Blood Bag CPD SAG-M 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3BG456Q0Y Blood Bag CPD SAG-M TAB 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4BG456Q0Y Blood Bag CPD SAG-M TAB 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4CG456Q0Y Blood Bag CPD SAG-M TAB CRC Filter inline 450 ml 4 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-5CG456Q0Y Blood Bag CPD SAG-M TAB CRC Filter inline 450 ml 5 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-5RG456Q0Y Blood Bag CPD SAG-M TAB CRC Filter inline 450 ml 5 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD356S0Y Blood Bag CPDA-1 350 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD456S0Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| PB-3CD356S0Y Blood Bag CPDA-1 350 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3CD456S0Y Blood Bag CPDA-1 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3AG456S0Y Blood Bag CPD SAG-M 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3BG456S0Y Blood Bag CPD SAG-M TAB 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4AG456S0Y Blood Bag CPD SAG-M 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4BG456S0Y Blood Bag CPD SAG-M TAB 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4CG456S0Y Blood Bag CPD SAG-M TAB CRC Filter inline 450 ml 4 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4CG506S0Y Blood Bag CPD SAG-M TAB CRC Filter inline 500 ml 4 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4CG506S9Y Blood Bag CPD SAG-M TAB CRC Filter inline 500 ml 4 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4RG456S0Y Blood Bag CPD SAG-M TAB CRC Filter inline 450 ml 4 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| PB-5RG456S0Y Blood Bag CPD SAG-M TAB CRC Filter inline 450 ml 5 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4WG456S0Y Blood Bag CPD SAG-M Inline Filter WB-RP 450ml | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4WG506S0Y Blood Bag CPD SAG-M Inline Filter WB-RP 500ml | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4WO456S0Y Blood Bag CPD SAG-M-2(OPTISOL) Inline Filter WB-RP 450ml | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-5CG456S0Y Blood Bag CPD SAG-M TAB CRC Filter inline 450 ml 5 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456U0Y Blood Bag CPDA-1 450 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD456U0Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3AG456U0Y Blood Bag CPD SAG-M 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD256V0B Blood Bag CPDA-1 250 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456V0Y Blood Bag CPDA-1 450 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| PB-2CD356V0Y Blood Bag CPDA-1 350 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD456V0Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3AO456V0Y Blood Bag CPD OPTISOL 450ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1CD456Z8Y Blood Bag CPDA-1 450 ml Single Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD456Z0Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-2CD456Z8Y Blood Bag CPDA-1 450 ml Double Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3CD456Z0Y Blood Bag CPDA-1 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3CD456Z8Y Blood Bag CPDA-1 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3AO456Z0Y Blood Bag CPD SAGM-2 (OPTISOL) 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3AO456Z8Y Blood Bag CPD SAG-M-2(OPTISOL) 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-3BO456Z0Y Blood Bag CPD SAG-M-2(OPTISOL) TAB 450 ml Triple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| PB-4CD456Z0Y Blood Bag CPDA-1 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4CD456Z8Y Blood Bag CPDA-1 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4AO456Z0Y Blood Bag CPD SAG-M-2(OPTISOL) 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4AO456Z8Y Blood Bag CPD SAG-M-2(OPTISOL) 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4BO456Z0Y Blood Bag CPD SAG-M-2(OPTISOL) TAB 450 ml Quadruple Bag | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4RO456Z0Y Blood Bag CPD SAG-M-2(OPTISOL) TAB CRC Filter inline 450 ml 4 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-5RO456Z0Y Blood Bag CPD SAG-M-2(OPTISOL) TAB CRC Filter inline 450 ml 5 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4RO356J0Y Blood Bag CPD SAGM-2 TAB CRC Filter inline 350 ml 4 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4RO456J0Y Blood Bag CPD SAGM-2 TAB CRC Filter inline 450 ml 4 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| PB-4WO456J0Y Blood Bag CPD SAG-M-2(OPTISOL) Inline Filter WB-RP 450ml | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-5RO356J0Y Blood Bag CPD SAGM-2 TAB CRC Filter inline 350 ml 5 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-5RO456J0Y Blood Bag CPD SAGM-2 TAB CRC Filter inline 450 ml 5 Bag System | Class III | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4TR150M8S Blood Bag Transfer 150 ml Quadruple Bag for Aliquoting | Class IIb excluding Class IIb implantable non-WET | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1TR301M8Y Blood Bag Transfer 300 ml Single Bag | Class IIb excluding Class IIb implantable non-WET | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1TR301Q8Y Blood Bag Transfer 300 ml Single Bag | Class IIb excluding Class IIb implantable non-WET | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1TR151Z8B Blood Bag Transfer 150 ml Single Bag | Class IIb excluding Class IIb implantable non-WET | N/A | SGS Belgium NV - IN19/818843705 |
| PB-1TR301Z8Y Blood Bag Transfer 300 ml Single Bag | Class IIb excluding Class IIb implantable non-WET | N/A | SGS Belgium NV - IN19/818843705 |
| PB-4TR150Z8B Blood Bag Transfer 150 ml Quadruple Bag for Aliquoting | Class IIb excluding Class IIb implantable non-WET | N/A | SGS Belgium NV - IN19/818843705 |

**Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| N/A | N/A | N/A | N/A |

## Confirmation Letter Revision History

| Date | Action |
|---|---|
| 2023/07/17 | First issue under concession MD23-18 |
| 2024/11/05 | Amended: SGS Belgium MDD certificate IN19/818843705 was transferred to BSI NL according to Article 120 2023/607 and BSI is responsible for the appropriate surveillance of the devices listed under the Directive. All the Blood Bag and Transfer Bag configurations/catalogue numbers are listed and transferred from table 2 to table 1. The Class I device Blood Monitor was removed from the scope of the letter and MDD surveillance is no longer being performed. |

# Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

| | |
|---|---|
| Manufacturer name | TERUMO PENPOL Private Limited |
| Manufacturer address and contact details | Terumo Penpol Private Limited<br>Puliyarakonam<br>Thiruvananthapuram, India-695 573<br><br>Contact Persons:<br>Sarada Jayakrishnan(PRRC-Quality)<br>Jaya J Nair (PRRC-Regulatory)<br>Phone:+914713015500 |
| Single Registration Number (SRN) (if available) | IN-MF-000001071 |
| Authorised Representative name (if applicable) | Terumo BCT Europe N.V. |
| Authorised Representative address and contact details | Terumo BCT Europe N.V.<br>Ikaroslaan 41, – 1930 ZAVENTEM, Belgium.<br>Contact Person: Serge Tabet<br>Phone: +3227150590 |
| Single Registration Number (SRN) (if available) | BE-AR-000001030 |

| | |
|---|---|
| Notified body name (if applicable) | SGS Belgium NV |
| Notified body number (if applicable) | 1639 |
| Directive Certificate number(s) to which this confirmation is made (if applicable) | IN19/818843705 |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 08 August 2023 |
| End date of extended validity/transition period | As per attached schedule |

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

☐ Expired/expires *after* 20 March 2023:

Devices Included under MDR application.

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body , ie before 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement(s) is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR .

Devices not included under MDR application.

☐ We did not lodge an application for conformity assessment, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

☐ A QMS in accordance with Article 10(9) MDR is in place.

- **Device(s) as listed in the attached schedule**
  - The device(s) continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

Company Name : TERUMO PENPOL Private Limited

Date: 09-11-2023

Rev:01

**Sarada Jayakrishnan**

General Manager -Quality & PRRC-Quality

Email: Sarada.J@terumobct.com

**Jaya J Nair**

Manager-Regulatory Affairs & PRRC Regulatory

Email: Jaya.Nair@terumobct.com

**Schedule of Devices**

The above Manufacturer's Declaration is valid for the following devices included under MDR application (Product List -Annexure 1)

| **Identification of the device(s)** (e.g., device name, family/group name device model or catalogue number) | **Directive Certificate number(s) to which this confirmation is made** (if applicable) | **Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable) | **Notified Body name and number that issued the Directive Certificate** (if applicable) | **Notified Body name and number where the MDR application was lodged/contract signed** (if applicable) | **End date of extended validity / transition period** | **Substitute Device(s)** (if applicable) |
|---|---|---|---|---|---|---|
| 89040093BloodBags8N | IN19/818843705 | 08th August 2023 | SGS Belgium NV | BSI Group The Netherlands B.V. | 31 December 2027 | NA |
| 89040093TransferBagM7 | IN19/818843705 | 08th August 2023 | SGS Belgium NV | BSI Group The Netherlands B.V. | 31 December 2028 | NA |

The above Manufacturer's Declaration is valid for the following devices not included under MDR application(Product List -Annexure 2)

| **Identification of the device(s)** (e.g., device name, family/group name device model or catalogue number) | **Directive Certificate number(s) to which this confirmation is made** (if applicable) | **Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable) | **Notified Body name and number that issued the Directive Certificate** (if applicable) | **Notified Body name and number where the MDR application was lodged/contract signed** (if applicable) | **End date of extended validity / transition period** | **Substitute Device(s)** (if applicable) |
|---|---|---|---|---|---|---|
| 89040093BloodBags8N | IN19/818843705 | 08th August 2023 | SGS Belgium NV | NA | 26 May 2024 | NA |
| 89040093TransferBagM7 | IN19/818843705 | 08th August 2023 | SGS Belgium NV | NA | 26 May 2024 | NA |

| | Annexure -1 | |
|---|---|---|
| | Catalogs included in the MDR submission | End date for extension(subject to Regulatory approval in countries) |
| 1 | PB-1CD156M5S | 31-Dec-27 |
| 2 | PB-1CD256E8B | 31-Dec-27 |
| 3 | PB-1CD256M5S | 31-Dec-27 |
| 4 | PB-1CD256M8B | 31-Dec-27 |
| 5 | PB-1CD256V0B | 31-Dec-27 |
| 6 | PB-1CD356E8Y | 31-Dec-27 |
| 7 | PB-1CD456I9Z | 31-Dec-27 |
| 8 | PB-1CD456L8Y | 31-Dec-27 |
| 9 | PB-1CD456M0Y | 31-Dec-27 |
| 10 | PB-1CD456M0Z | 31-Dec-27 |
| 11 | PB-1CD456M8Y | 31-Dec-27 |
| 12 | PB-1CD456Q2Y | 31-Dec-27 |
| 13 | PB-1CD456U0Y | 31-Dec-27 |
| 14 | PB-1CD456V0Y | 31-Dec-27 |
| 15 | PB-1CD456Z8Y | 31-Dec-27 |
| 16 | PB-2CD356M0Y | 31-Dec-27 |
| 17 | PB-2CD356M8Y | 31-Dec-27 |
| 18 | PB-2CD356S0Y | 31-Dec-27 |
| 19 | PB-2CD356V0Y | 31-Dec-27 |
| 20 | PB-2CD456L8Y | 31-Dec-27 |
| 21 | PB-2CD456M0Y | 31-Dec-27 |
| 22 | PB-2CD456M8Y | 31-Dec-27 |
| 23 | PB-2CD456Q0Y | 31-Dec-27 |
| 24 | PB-2CD456S0Y | 31-Dec-27 |
| 25 | PB-2CD456U0Y | 31-Dec-27 |
| 26 | PB-2CD456V0Y | 31-Dec-27 |
| 27 | PB-2CD456Z0Y | 31-Dec-27 |
| 28 | PB-2CD456Z8Y | 31-Dec-27 |
| 29 | PB-3AG456E0Y | 31-Dec-27 |
| 30 | PB-3AG456M0Y | 31-Dec-27 |
| 31 | PB-3AG456M8Y | 31-Dec-27 |
| 32 | PB-3AG456Q0Y | 31-Dec-27 |
| 33 | PB-3AG456S0Y | 31-Dec-27 |
| 34 | PB-3AG456U0Y | 31-Dec-27 |
| 35 | PB-3AO356E0Y | 31-Dec-27 |
| 36 | PB-3AO456V0Y | 31-Dec-27 |
| 37 | PB-3AO456Z0Y | 31-Dec-27 |
| 38 | PB-3AO456Z8Y | 31-Dec-27 |
| 39 | PB-3BG456A0Y | 31-Dec-27 |
| 40 | PB-3BG456M0Y | 31-Dec-27 |
| 41 | PB-3BG456Q0Y | 31-Dec-27 |
| 42 | PB-3BG456S0Y | 31-Dec-27 |
| 43 | PB-3BO456Z0Y | 31-Dec-27 |
| 44 | PB-3CD356M8Y | 31-Dec-27 |
| 45 | PB-3CD356S0Y | 31-Dec-27 |
| 46 | PB-3CD456L8Y | 31-Dec-27 |
| 47 | PB-3CD456M0Y | 31-Dec-27 |

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|---|---|---|
| 48 | PB-3CD456M8Y | 31-Dec-27 |
| 49 | PB-3CD456Q0Y | 31-Dec-27 |
| 50 | PB-3CD456S0Y | 31-Dec-27 |
| 51 | PB-3CD456Z0Y | 31-Dec-27 |
| 52 | PB-3CD456Z8Y | 31-Dec-27 |
| 53 | PB-4AG456E0Y | 31-Dec-27 |
| 54 | PB-4AG456M0X | 31-Dec-27 |
| 55 | PB-4AG456M0Y | 31-Dec-27 |
| 56 | PB-4AG456S0Y | 31-Dec-27 |
| 57 | PB-4AO456E0X | 31-Dec-27 |
| 58 | PB-4AO456Z0Y | 31-Dec-27 |
| 59 | PB-4AO456Z8Y | 31-Dec-27 |
| 60 | PB-4BG456A0Y | 31-Dec-27 |
| 61 | PB-4BG456L0Y | 31-Dec-27 |
| 62 | PB-4BG456M0Y | 31-Dec-27 |
| 63 | PB-4BG456Q0Y | 31-Dec-27 |
| 64 | PB-4BG456S0Y | 31-Dec-27 |
| 65 | PB-4BO456E0Y | 31-Dec-27 |
| 66 | PB-4BO456Z0Y | 31-Dec-27 |
| 67 | PB-4CD456Z0Y | 31-Dec-27 |
| 68 | PB-4CD456Z8Y | 31-Dec-27 |
| 69 | PB-4CG456Q0Y | 31-Dec-27 |
| 70 | PB-4CG456S0Y | 31-Dec-27 |
| 71 | PB-4CG506S0Y | 31-Dec-27 |
| 72 | PB-4CG506S9Y | 31-Dec-27 |
| 73 | PB-4RG456S0Y | 31-Dec-27 |
| 74 | PB-4RO356J0Y | 31-Dec-27 |
| 75 | PB-4RO456J0Y | 31-Dec-27 |
| 76 | PB-4RO456Z0Y | 31-Dec-27 |
| 77 | PB-4WG456S0Y | 31-Dec-27 |
| 78 | PB-4WG506S0Y | 31-Dec-27 |
| 79 | PB-4WO456J0Y | 31-Dec-27 |
| 80 | PB-4WO456S0Y | 31-Dec-27 |
| 81 | PB-5CG456Q0Y | 31-Dec-27 |
| 82 | PB-5CG456S0Y | 31-Dec-27 |
| 83 | PB-5RG456Q0Y | 31-Dec-27 |
| 84 | PB-5RG456S0Y | 31-Dec-27 |
| 85 | PB-5RO356J0Y | 31-Dec-27 |
| 86 | PB-5RO456J0Y | 31-Dec-27 |
| 87 | PB-5RO456Z0Y | 31-Dec-27 |
| 88 | PB-1TR151Z8B | 31-Dec-28 |
| 89 | PB-1TR301M8Y | 31-Dec-28 |
| 90 | PB-1TR301Q8Y | 31-Dec-28 |
| 91 | PB-1TR301Z8Y | 31-Dec-28 |
| 92 | PB-4TR150M8S | 31-Dec-28 |
| 93 | PB-4TR150Z8B | 31-Dec-28 |

| | Annexure -2 | |
|---|---|---|
| | Non-MDR Catalogues | **End date for extension** |
| 1 | PB-1CD106J8B | 26-May-24 |
| 2 | PB-1CD256M2B | 26-May-24 |
| 3 | PB-1CD256Z8B | 26-May-24 |
| 4 | PB-1CD356J0Y | 26-May-24 |
| 5 | PB-1CD356J5Y | 26-May-24 |
| 6 | PB-1CD356J8Y | 26-May-24 |
| 7 | PB-1CD456J8Y | 26-May-24 |
| 8 | PB-1CD456Z4Y | 26-May-24 |
| 9 | PB-1PD156J5S | 26-May-24 |
| 10 | PB-1PD156J8S | 26-May-24 |
| 11 | PB-1PD256J8S | 26-May-24 |
| 12 | PB-1PD256Z9S | 26-May-24 |
| 13 | PB-2CD356J0Y | 26-May-24 |
| 14 | PB-2CD356J5Y | 26-May-24 |
| 15 | PB-2CD356J8Y | 26-May-24 |
| 16 | PB-2CD356M2Y | 26-May-24 |
| 17 | PB-2CD456J0Y | 26-May-24 |
| 18 | PB-2CD456J8Y | 26-May-24 |
| 19 | PB-2CD456M2Y | 26-May-24 |
| 20 | PB-2CD456Z4Y | 26-May-24 |
| 21 | PB-3AO356J0Y | 26-May-24 |
| 22 | PB-3AO356J8X | 26-May-24 |
| 23 | PB-3AO356J8Y | 26-May-24 |
| 24 | PB-3AO456J0Y | 26-May-24 |
| 25 | PB-3AO456J8X | 26-May-24 |
| 26 | PB-3AO456J8Y | 26-May-24 |
| 27 | PB-3AO456Z4Y | 26-May-24 |
| 28 | PB-3BO356J0Y | 26-May-24 |
| 29 | PB-3BO356J8Y | 26-May-24 |
| 30 | PB-3BO456J0Y | 26-May-24 |
| 31 | PB-3BO456J8Y | 26-May-24 |
| 32 | PB-3CD356J5Y | 26-May-24 |
| 33 | PB-3CD356J8Y | 26-May-24 |
| 34 | PB-3CD456J0Y | 26-May-24 |
| 35 | PB-3CD456J8Y | 26-May-24 |
| 36 | PB-3CD456Z4Y | 26-May-24 |
| 37 | PB-4AO356J0X | 26-May-24 |
| 38 | PB-4AO356J8X | 26-May-24 |
| 39 | PB-4AO356J8Y | 26-May-24 |
| 40 | PB-4AO456J0X | 26-May-24 |
| 41 | PB-4AO456J8X | 26-May-24 |
| 42 | PB-4AO456J8Y | 26-May-24 |
| 43 | PB-4AO456Z2Y | 26-May-24 |
| 44 | PB-4BO356J0Y | 26-May-24 |
| 45 | PB-4BO356J8Y | 26-May-24 |
| 46 | PB-4BO456J0Y | 26-May-24 |
| 47 | PB-4BO456J8Y | 26-May-24 |
| 48 | PB-4CD356J8Y | 26-May-24 |
| 49 | PB-4CD456J0X | 26-May-24 |

| | | |
|---|---|---|
| 50 | PB-4CD456J8X | 26-May-24 |
| 51 | PB-4CD456J8Y | 26-May-24 |
| 52 | PB-4CD456Z4Y | 26-May-24 |
| 53 | PB-4CG456M0B | 26-May-24 |
| 54 | PB-5CD456J8Y | 26-May-24 |
| 55 | PB-5CO356J0Y | 26-May-24 |
| 56 | PB-5CO456J0Y | 26-May-24 |
| 57 | PB-5CO456Z0B | 26-May-24 |
| 58 | PB-1TR050M6B | 26-May-24 |
| 59 | PB-1TR101J8B | 26-May-24 |
| 60 | PB-1TR151Q8B | 26-May-24 |
| 61 | PB-1TR301J8Y | 26-May-24 |
| 62 | PB-1TR301Q8B | 26-May-24 |
| 63 | PB-1TR301Z8B | 26-May-24 |
| 64 | PB-1TR451J8Y | 26-May-24 |