Poly Medicure Limited
Plot No.104-105, Sector-59, HSIIDC Industrial Area,
Ballabgarh, Faridabad - 121004, Haryana (INDIA)
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POLYMED

EU DECLARATION OF CONFORMITY

1. Document No.: PML/MD/DOC/1.03, Rev. 03
2. This declaration of conformity is issued under the sole responsibility of Poly Medicure Limited.
3. **Address of manufacturing site:** Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana-121004, INDIA. info@polymedicure.com
4. **European Authorized Representative:** Obelis S.A, Boulevard Général Wahis 53, 1030,Brussels, Belgium, regulatory@obelis.net, SRN: BE-AR-000000106.
5. **CE Certificate number**: G10 041938 0011, Rev.00, Valid upto: 23.02.2030
6. **Product Name:** Infusion Sets (IV Administration Set)
7. **Product Code and Variants:** Please refer attached Annexure-1.
8. **Intended purpose of device**: The Infusion Sets are used for infusion of fluid such as parenteral nutrition and administration of other drugs or medicines into human circulating system by using intravenous catheter or cannula.
9. The device Infusion Sets complies with the Regulation (EU) 2017/745 and fulfills the applicable General Safety and Performance Requirements set out in Annexure-1 of the Regulation.
10. Conformity Assessment Procedure: Annexure-IX, Chapter I & III.
11. **SRN:** IN-MF-000043009
12. **Basic UDI:** 890209514002DW
13. **MDN Code:** 1202
14. **EMDN Code:** A03010101
15. **Reference National / International Standard**: EN ISO 13485:2016+ A11:2021, EN ISO 14971:2019/ A11:2021, EN ISO 15223-1:2021/ *Amd 1:2025*, EN ISO 10993-1:2020, EN ISO 11135:2014/ A1:2019, ISO 11737-1:2018/ Amd 1:2021, EN ISO 11737-2:2020, EN ISO 11607-1:2020/A11:2023, EN ISO 11607-2:2020/A11:2023, ISO 8536-4:2019, ISO 8536-8:2015, ISO 80369-7:2021, ISO 9626:2016, ISO 2859-1:1999/Amd 1:2011, ISO 14644-1:2015, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 20417:2021.
16. **Device Class:** IIa, Classification Rule: Rule- 7
17. The company and its authorized representative shall fulfil the obligations imposed by European Medical Device Regulation 2017/745 & ensure that the product shall meet all provisions as applicable.
18. **Notified Body:** 'TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany', Notified Body No.-0123.

Place: Faridabad
Date of Issue: 28.04.2026
Attachment: Annexure-1

RD Sharma
Sr. GM- CQRA & PRRC
On behalf of POLY MEDICURE LIMITED

ANNEXURE-1

S. No.	Polymed Product codes	Terumo Product Codes	Polymed Description
1.	14370	PT+PU400WY	IV Infusion Set, Vented, 57mm Drip Chamber, Long Orange roller clamp, Thumb support Y-Injection port, Rotating Luer Lock with PE cap, AFF Clip, DEHP Free Tube-220cm-Blister Pack
2.	14380	PT+PU402WY	IV Infusion Set, Vented, 57mm Drip Chamber, Long Orange roller clamp, Needle free Y-Injection port, Rotating Luer Lock with PE cap, AFF clip, DEHP Free Tube-220cm-Blister Pack