

## Poly Medicure Limited

Plot No.104-105, Sector-59, HSIIDC Industrial Area,  
Ballabgarh, Faridabad - 121004, Haryana (INDIA)  
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22<sup>nd</sup> October 2021

### EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabgarh - 121004, Faridabad, INDIA.

Hereby declare and take responsibility to ensure that the following product:

S. No.	Product Description	Medical Device Class	Polymed Product Codes
01	Stop cock with/ without Extension line	IIa	13027, 13024, 13505, 13506
05	Extension line	IIa	13198, 13203, 13204
06	Manifolds with/ without Extension line	IIa	13712, 13743, 13745
07	Infusion Set	IIa	14113, 14116
08	Transfusion Sets (BT Sets)	IIa	70152

As per Annexure – IX of the Medical Device Directive comply with the product standards/ requirements and, meet the essential requirements according to Annexure- I of the Council Directive 93/42/EEC of 14<sup>th</sup> June 1993 as amended by 2007/47/EC concerning medical devices.

Conformity Assessment Procedure was carried out according to Annexure - II excluding section 4 of the MDD and is certified by the following Notified Body.

Name, Address & No. : TÜV SÜD Product Service GmbH,  
Ridlerstraße 65, 80339, Munich, Germany  
Notified Body Number 0123,

CE Certificate No. : G1 041938 0007

European Authorized Representative Address : OBELIS S.A.  
Boulevard Général Wahis 53,  
B-1030, Brussels, Belgium,  
mail@obelis.net

  
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Ramdas Sharma  
DGM - Quality  
On behalf of POLY MEDICURE LTD. Faridabad