

## Poly Medicure Limited

Plot No.104-105, Sector-59, HSIIDC Industrial Area,  
Ballabgarh, Faridabad - 121004, Haryana (INDIA)  
T: +91-129-3355070, 4287000, F: +91-129-2307007, 2309102  
E: info@polymedicure.com W: polymedicure.com



10<sup>th</sup> September 2021

### EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Plot No. 104-105 / 115-116, Sector-59, HSIIDC Industrial Area, Ballabgarh - 121004, Faridabad, INDIA.

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

S. No.	Product Description	Device Class	Product Codes
01	IV Cannula/Catheter with/ without Safety Features	IIa	11010, 11011 11013, 11015 11016, 11017
02	Extension Lines	IIa	13187, 13123


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 0419380007

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