

Poly Medicure Limited

Plot No.104-105, Sector-59, HSIIDC Industrial Area,
Ballabgarh, Faridabad - 121004, Haryana (INDIA)
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10th 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 14th 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



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