Poly Medicure Limited
Plot No.104-105, Sector-59, HSIIDC Industrial Area,
Ballabgarh, Faridabad - 121004, Haryana (INDIA)
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POLYMED MEDICAL DEVICES
We Care As We Cure

01 July 2020

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:

- UNIPERF

S. No.	Product Description	Polymed Reference Code	Asept Reference Code
1	Infusion set with injection site + male rotating luer lock + purge filter	1029.1	202090
2	Infusion set with injection site + male rotating luer lock + purge filter + needle (LPPR)	1029.2	202091
3	Infusion set with 3 ways stopcocks + male rotating luer lock + purge filter	1029.4	202092
4	Infusion set with 3 ways stopcocks + male rotating luer lock + purge filter + needle (LPPR)	1029.5	202093

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 (Module – H) 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

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