

Poly Medicure Limited

Plot No.104-105, Sector-59, HSIIDC Industrial Area,
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27 June 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:

- UNICAP

S. No.	Product Description	Medical Device Class	Polymed Reference Code	Asept Reference code
01	Male Luer lock cap (Luer caps)	IIa	13353	202110
02	Injection site cap (Luer caps)	IIa	13555	202111

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