

Poly Medicure Limited

Plot No.104-105, Sector-59, HSIIDC Industrial Area,
Ballabgarh, Faridabad - 121004, Haryana (INDIA)
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09 May 2019

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	Medical Device Class
1.	Three way stopcock (with and without extension tube)	IIa
2.	Extension tubes	IIa
3.	IV Administration Set	IIa
4.	Urine bag	Is
5.	IV cannula with and without safety features	IIa
6.	Central venous catheter kit	III

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. : DNV GL Nemko Presafe AS,
Veritasveien 3, 1363, HOVIK, Norway
Notified Body Number 2460,

CE Certificate No. : Plot No.104-105 11186-2017-CE-IND-NA-PS
Plot No.115-116 11187-2017-CE-IND-NA-PS

European Authorized Representative Address : OBELIS S.A.
Boulevard Général Wahis 53,
B-1030, Brussels, Belgium,
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Ramdas Sharma
AGM - Quality
On behalf of POLY MEDICURE LTD. Faridabad