

30th July 2020**EC DECLARATION OF CONFORMITY**

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

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

- UNIWAYS

S. No.	Product Description	Medical Device Class	Polymed Reference Code	Asept Reference Code
1	3 Ways stopcocks	IIa	1021	202083
2	3 Ways stopcocks with PVC Extension Line 3 X 4.1 X 10cm with male rotating luer lock	IIa	1021.01	202084
3	3 Ways stopcocks with PVC Extension Line 3 X 4.1 X 25cm with male rotating luer lock	IIa	1021.03	202085
4	3 Ways stopcocks with PVC Extension Line 3 X 4.1 X 50cm with male rotating luer lock	IIa	1021.05	202086
5	3 Ways stopcocks with PVC Extension Line 3 X 4.1 X 80cm with male rotating luer lock	IIa	1021.08	202087
6	3 Ways stopcocks with PVC Extension Line 3 X 4.1 X 100cm with male rotating luer lock	IIa	1021.10	202088
7	3 Ways stopcocks with PVC Extension Line 3 X 4.1 X 150cm with male rotating luer lock	IIa	1021.15	202089

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.

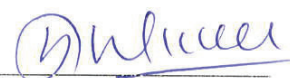
: TÜV SÜD Product Service GmbH,
Ridlerstraße 65, 80339, Munich, Germany
Notified Body Number 0123,

CE Certificate No.

: G1 041938 0007

European Authorized Representative Address

: OBELIS S.A.
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mail@obelis.net



SS Rawat

Sr. GM - Quality

On behalf of POLY MEDICURE LTD. Faridabad