

27th October 2021

EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Plot No. 010-018 & 010-19, Mahindra World City (Jaipur) Ltd. Multi-product SEZ, Distt. Jaipur – 302037, Rajasthan, (India).

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

Sr. No.	Product Description	Device Class	Polymed Reference Code	Customer Reference Code
01	Suction Catheter	IIa	20201, 20202, 20203, 20204, 20205, 20206 20207, 20208, 20209, 20210, 20211, 20212, 20213, 20214, 20215, 20216, 20217, 20218, 20219, 20220, 20221, 20222, 20223, 20224, 20225, 20226, 20227, 20228, 20229, 20230, 20231, 20232, 20233, 20234, 20235, 20236, 20237, 20238, 20239, 20240, 20241, 20242, 20243, 20244, 20245, 20246, 20247, 20248, 20249, 20250, 20251, 20252, 20253, 20254, 20255, 20256, 20257, 20258, 20259, 20260, 20261, 20262, 20263, 20264	OSC-1205/35, OSC-1205/48, OSC-1205/60, OSC-1206/35, OSC-1206/48, OSC-1206/60, OSC-1207/35, OSC-1207/48, OSC-1207/60, OSC-1208/35, OSC-1208/48, OSC-1208/60, OSC-1210/35, OSC-1210/48, OSC-1210/60, OSC-1212/35, OSC-1212/48, OSC-1212/60, OSC-1214/35, OSC-1214/48, OSC-1214/60, OSC-1216/35, OSC-1216/48, OSC-1216/60, SC-1105/48, SC-1105/60, SC-1106/48, SC-1106/60, SC- 1108/48, SC-1108/60, SC-1110/48, SC-1110/60, SC-1112/48, SC-1112/60, SC- 1114/48, SC-1114/60, SC-1116/48, SC-1116/60, SC-1118/48, SC-1118/60, OSC -1505/48, OSC -1505/53, OSC -1505/60, OSC -1506/48, OSC -1506/53, OSC -1506/60, OSC -1508/48, OSC -1508/53, OSC -1508/60, OSC -1510/48, OSC -1510/53, OSC -1510/60, OSC -1512/48, OSC -1512/53, OSC -1512/60, OSC -1514/48, OSC -1514/53, OSC -1514/60, OSC -1516/48, OSC -1516/53, OSC -1516/60, OSC -1518/48, OSC -1518/53, OSC -1518/60

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.

: G2 105735 0004

European Authorized Representative Address

: OBELIS S.A.
Boulevard Général Wahis 53,
B-1030, Brussels, Belgium, mail@obelis.net



SS Rawat
Head - Quality

On behalf of POLY MEDICURE LTD. Faridabad