Poly Medicure Limited

Mahindra World City, Special Economic Zone (SEZ) Plot No. PA 010-019, Light Engineering Sector, Jaipur - 302037, Rajasthan (INDIA), T: +91-141-3309900 E: info@polymedicure.com W: polymedicure.com



18th Dec, 2020

EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Mahindra World City, Special Economic Zone, Plot No.- PA 010-019, Light Engineering Sector, Jaipur -302037, Rajasthan, INDIA.

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

S. No.	Product Description	Medical Device Class
1	Suction Catheter	IIa
2	Infant feeding Tube	IIa

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 – H2) 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 0002

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

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