

EU DECLARATION OF CONFORMITY

According to Art.19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer :	Manish Medi Innovation SY No. 150/2, No. 53,54, 55, 68, 69 and 70, Bannerghatta Main Road, ABT Layout, Hullahalli Village, CK Palya, Bannerghatta, Bengaluru Urban, Bengaluru – Karnataka 560083, INDIA. Unit 2: MANISH MEDI INNOVATION 10/9, 3 rd Main, 24 th Cross Sri Krishna Layout, Hulimavu, Bannerghatta Road Bangalore, Karnataka 560076, INDIA.
Trademark :	UROMED™
SRN:	IN-MF-000039093
European Representative:	Name : CMC MEDICAL DEVICE C/Horacio Lengo N° 18 CP 29006, Malaga – Spain
SRN:	ES-AR-000000293
Trade Name :	Guide Wire
Product Name :	Guide Wire
EMDN Code :	U0699
Basic UDI :	890615570GWYX
Classification acc. To MDR:	Class IIa, rule 7 of MDR Annex VIII
Applied Standard & Common Specification :	EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-7:2008, EN ISO 10993-11:2017, ISO 14644-1:2015, ISO 14644-2:2015, EN ISO 11135-1:2014, EN ISO 11737-1:2018, EN ISO 11737-2:2020, ISO 11138-2:2017, ISO 15223-1:2021, ISO 20417:2021, EN 556-1:2001, EN 556-2:2015, EN ISO 11607-1:2019, EN ISO 11607-2:2019, ISO 9001:2015, EN ISO 13485:2016, ISO 80369-7:2021, ASTM D1238,ASTM D638, ASTM D790A,ASTM D256, ASTM D3418,ASTM D648, ASTM D412, ASTM B117,ISO 9227,ASTM F1980-07:2011 USP 41, ASTM F88 ASTM F1886 ASTM F1929, ISO/TR 24971:2020, IEC 62366-1:2015, EN ISO 10993-18:2020, ISO/TR 20416:2020

Conformity assessment Procedure: Annex IX, MDR (2017/745)
Rule [X] of Annex IX of the Medical Devices Directive 93/42/EEC.

CE Certificate No. : G1 106376 0002 Rev.00

Name & ID of Notified Body : **TUV SUD Product service GmbH**
Ridlerstrabe 65, D-80339, Munchen, Germany
Number : 0123.

We, the manufacturer, here with declare under our sole responsibility that the above – mentioned products meets the provisions of the Regulation (EU) 2017/745 on medical devices regulation (MDR). All supporting documents are retained under the premises of the manufacturer



Nirmal Kumar K M
Managing Director