



SAMAY
Surgical

Mfg.: Orthopedic Implants & Instruments

An ISO 13485 Certified Company & CE

Survey No.212, Plote No.6, Parmar Metal Sreet, NH-8B, Veraval – Shapar – 360024 Dist. Rajkot, Gijarat, India
Ph.: 02827 252154 Mo.: +91 7878152154 Email: samay_surgical@yahoo.com Web: www.samaysurgical.com

Declaration of Conformity-Orthopedic Instruments

Manufacture's Name:	Samay Surgical
Manufacture's Address:	Survey No. 212, Plot No. 6, Nr. Patidar Plastic, Nh-8b, Shapar, VeravalRajkot -360024 Gujarat, India
Manufacture's SRN:	IN-MF-000013203
Product Name:	Orthopedic Instruments(Accessories for Installation of the Implants)(Refer Annexure I – Product List, as mentioned below)
Basic UDI-DI	In process
Brand Name	Samay
Applicable Directive	Annex VII – EC Declaration of Conformity of 93/42/EEC Medical Device Directives as amended 2007/47/EC
Classification	Class I – (Rule 6 – Surgically invasive devices – Transient Use)
Applicable Standards	EN ISO 14971:2019 EN ISO 15223:2021 EN ISO 20417:2021 EN ISO 13485:2016 EN ISO 14155:2020
EU Rep	CMC Medical & Drug S.L. C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain.Tel: +34 951 214 054 Email: info@cmcmmedicaldevices.com
EU Rep SRN	ES-AR-000000293
Product Certification Body	UK Cert, UK
Certification No.	CE-12499
Valid Till	25.12.2022
The undersigned declares that the above named products conform to the above Directives and Standards as applicable on the devices.	
Authorized Signatory 	
Name: Mr. Mahesh Godharasa Partner, Samay Surgical Date: 26/05/2021	