

DECLARATION OF CONFORMITY

Name and Description of Product	: Plates, Screws & Nails - Orthopedic Implants
Brands	: SHARMA
Category of Products	: Medical Devices (Orthopedic Implants)
Conformity Declared to Standard (s)	: ISO 5835:1991, ISO 6475:1989, ISO 9268:1988, ISO 5836:1988, ISO 9269:1988, ISO 9585:1990, ISO 15142-1:2003, ISO 15142-2:2003, ISO 15142-3:2003, ISO 12189:2008, ISO 18192-1:2011, ISO 18192-2:2010, ISO 5838-1:2013, ISO 5838-2:1991, ISO 5838-3:1993, ISO 8827:1988, ISO 14630: 2012, ISO 13485:2003, ISO 14644-1:1999, ISO 14644-2:2000, ISO 5832-1:2007, ISO 5832-3:1996, ASTM F136, ASTM F138, ASTM F139, ASTM F748, EN ISO 14971:2012, ISO 15223-1:2012, EN 1041:2008, ISO 11137-1:2006, ISO 11137-2:2013, ISO 11607-1:2006, ISO 11607-2:2006, ISO 11737-1: 2006, ISO 11737-2: 2009, ISO 10993-1: 2009, ISO 10993-5: 2009, ISO 10993-10: 2010, AISI 316L, ASTM A276, ISO 5832-3:1996, EN-980:2008
Classification of Product	: Class IIb (Sterile & Non-Sterile) (Rule 8 - Surgically invasive long term device used as implantable devices)
 Manufacturer	: ADDRESS: 445/A, G.I.D.C. Estate, Waghodia – 391 760, Vadodara, Gujarat, India.
Conformity Assessment procedure	: Annex II – Full Quality Assurance Excl. Section 4.

The undersigned declares that the above named product conforms to the above Directives and Standards as applicable on the devices.

Date: 22-01-2021

Name : Rajaram Yadav
Position : Manager – QA/RA

