



TECHNICAL CONSTRUCTION FILE (PSL/TCF/01)

Issue No. 01
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PARAMOUNT SURGIMED LIMITED
A-106, RIICO Industrial Area , Bhiwadi -
301019 , District –Alwar, Rajasthan, India

Title: Declaration of Conformity

Ref. No.: PSL-DOC-001A/ISSUE-01/Rev-02, Dated-22-07-2022

DOC is according to annex –VIII, Rule no.1, Class 1 of the regulation (EU) 2017/745 concerning medical devices.
We



PARAMOUNT SURGIMED LIMITED

A-106, RIICO Industrial Area, Bhiwadi -301019, District –Alwar, Rajasthan, India; SRN No. IN-MF-000021682
Declare under our sole responsibility that the product:

Name of Device	Catalogue code	Basic UDI-DI	Classification		Sterile	Variants/ Model	Lot	Mfg. Date	Exp. Date
			Rule	Class					
Blade Handles	Gauge Metal Handle (PGMH)	8903175PGMH8D	Rule 1, Annex VIII	1	Non- Sterile	XXXX	XXXX	MM- YYYY	NA

Meets the provisions of the regulation (EU) 2017/745 concerning medical devices which apply to them:

The MD is in Class I, according to annex-VIII of the Medical Device Rule

List of applicable standards:

Harmonized standard: Harmonized EN ISO 14971: 2019, EN 62366:2008, EN ISO 10993 –1: 2009/AC:2010, EN ISO 10993-4:2009, EN ISO 10993-5: 2009, EN ISO 10993-12:2012, EN ISO 10993-23:2021, EN ISO 11607-1:2019, EN ISO 11607-2:2019, EN ISO 13485:2016/ A11:2021, EN ISO 11737-1: 2018 A1:2021, EN ISO 11737-2:2020, EN ISO 11140- 1 :2009, EN 1041:2008, EN ISO 15223-1:2021, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN 27740: 1992/ AC 1996,

Non- Harmonized standard : ISO 7153-1:2016, BS 2982:1992, ISO 2859-1:1999, IS 6263:1972, USP 40, ISO 14644-1:2015, ISO 14644 – 2 : 2015, ISO 14644-3:2019, ISO 14644-4:2001, ISO 14644-5:2004, ISO 14644-8: 2022, ISO 14644-9:2022, ISO 14644-10:2022, ISO 7740:1985, ISO/TC170/SC N 72, BS 5194- 1:1991, IS-10150 : 1981, ,IP 2002 ,ISO 14644-7:2004,ISO 14698-1:2003,ISO 14698-2:2003, ISO/IEC 62366:2015+ A1:2020 , ISO 10993-10:2010, ISO 6507-1:2018, ISO 20417 : 2021, ISO 11140-1:2014, ISO 2247:2000, ISO 780:2015,



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For PARAMOUNT SURGIMED LIMITED

Sign & date of issue: 22-07-2022

Name: Manoj Dhiman

Position: Manager QA