



# PARAMOUNT SURGIMED LIMITED

A-106 RIICO Industrial Area, Bhiwadi Rajasthan-301019

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CIN. : U74899DL1993PLC055981

**Ref. No.: PSL-DOC/V-2A / Issue No. 06/ Rev-04, Dated-19-10-2022**

According to annex –II excluding section IV of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices we:



## PARAMOUNT SURGIMED LIMITED

A-106, RIICO Industrial Area, Bhiwadi -301019, District –Alwar, Rajasthan, India

Declare under our sole responsibility that the product:

Name of Device	Classification		Sterile	Variants/ Model	Lot	Mfg. Date	Exp. Date
	Rule	Class					
<b>Disposable Scalpel made of Stainless Steel</b> <b>Order No. 20544</b> <b>(Brand- Paramount)</b>	Rule 6, Annex IX	IIa	Sterile by Gamma Irradiation	10	HB0168	2024/05	2029/04
				12	HB0169	2024/05	2029/04
				18	HB0170	2024/05	2029/04
				20	HB0171	2024/05	2029/04
				21	HB0172	2024/05	2029/04
				22	HB0173	2024/05	2029/04
				23	HB0174	2024/05	2029/04
				24	HB0175	2024/05	2029/04

Meets the provisions of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices which apply to them:

The MD is in Class IIa, according to annex-IX of the Medical Device Directive and certified as per article 11.3 (a). We have presented our product as well as our quality management system to the notified body 'DNV<sup>2460</sup>' for assessment as per the requirements of MDD 93/42/EEC as amended by 2007/47/EC.

Following standards were used to prove the products conformity with the essential requirements of the Directive:

**Harmonized** EN ISO 14971: 2019, EN ISO 14155: 2011/ AC 2011, 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 11607-1:2009, EN ISO 11607-2:2006, EN ISO 13485:2016, EN ISO 11737-1: 2018 A1:2021, EN ISO 11737-2:2009, 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-** ISO 7153-1:2016, BS 2982:1992, ISO 2859-1:2003, IS 6263:1972, USP 40, ISO 14644-1 :2015, ISO 14644 – 2 : 2015, ISO 14644-8: 2013, ISO 14644-9 : 2012, ISO 14644-10 : 2013, BS EN 27740:1992,ISO/TC170/SC N 72, BS 5194(Part 1):1991, FSC 6515, 6520 GG-H- 0080a (DSA-DM), IS-10150 : 1981,BS EN-868-5 : 2009,IP 2002 ,ISO 14644-7:2004,ISO 14698-1:2003,ISO 14698-2:2003, , ISO 10993-10:2010, ISO 6507-1:2018, Signatory established within the EU who has been empowered to enter into commitments on our behalf:

### NOTIFIED BODY:

**DNV Product Assurance AS, Veritasveien 1, N-1363 Høvik,**

**Post Box 161, N-1300, Sandvika, Phone-+47 67578800**

**Website: [www.dnv.com](http://www.dnv.com)**

**NOTIFIED BODY NO: 2460**

MDSS GmbH, Schiffgraben 41,

D-30175 Hannover, Germany

Tel. +49 511 6262 8630, Email: info@mdss.com



2460

**CE Certificate No: 10000400574-PA-NA-IND**

**Date of Issue: 15.09.2020**

**Valid till: 27 May 2024**

**For PARAMOUNT SURGIMED LIMITED**

**Sign & date of issue: 29.05.2024**

**Name: Manoj Dhiman**

**Position: Manager QA**

**Employee code: PS020**

**Regd. Office : 1, L.S.C., OKHLA INDL. AREA, OKHLA MAIN ROAD, PHASE-II, NEW DELHI - 110 020 (INDIA)**

**WORKS : A-106, RIICO INDUSTRIAL AREA, BHIWADI (RAJASTHAN)**