



# PARAMOUNT SURGIMED LIMITED

1, L.S.C., Okhla Industrial Area, Okhla Main Road Phase-II, New Delhi - 110020, India  
Tel. : +91-11-46436601, 40  
Email : sales@paramountblades.com  
Email : info@paramountsurgimedltd.com  
Email : exports@paramountdiaper.com

Website : www.paramountsurgimedltd.com  
Website : www.paramountsurgimed.com  
Website : www.paramountblades.com  
CIN. : U74899DL1993PLC055981

Ref. No.: PSL-DOC/V-1/ISSUE-07/Rev-02, Dated-20-04-21

## DECLARATION OF CONFORMITY

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>Gouge Blades in Carbon Steel (Brand- Ruck, Order no. 8516)</b>	Rule 6, Annex IX	IIa	Sterile by Gamma Irradiation	1	EA0682	2021/04	2026/03
				1	DA0433	2020/02	2025/01
				1	EA0715	2021/06	2026/05
				2	EA0716	2021/06	2026/05
				2	EA0683	2021/04	2026/03
				12	DA0272	2020/02	2025/01
				12	DA1313	2020/10	2025/09
				12	C10188	2019/03	2024/02
				1V	EA0717	2021/06	2026/05
				2V	EA0718	2021/06	2026/05
				2V	C10611	2019/05	2024/04
				2V	C10191	2019/03	2024/02
2V	C11828	2019/12	2024/11				

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<sub>2460</sub>' 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: 2012, 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: 2009, EN ISO 11737-2:2009, EN ISO 11140- 1 :2009, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN 27740: 1992/ AC 1996, EN ISO 11138-2 :2009

**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 3, N-1363 Høvik, Norway  
E-mail: [info@presafe.com](mailto:info@presafe.com)  
Website: [www.presafe.com](http://www.presafe.com)



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)

: PLOT NO. 33, SEC-14, PHASE-II, HSIIDC, IMT BAWAL, REWARI, (HARYANA)



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**NOTIFIED BODY NO: 2460**



MDSS GmbH, Schiffgraben 41,  
D-30175, Hannover, Germany  
Email: [info@mdss.com](mailto:info@mdss.com)

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

**Date of Issue: 15 September 2020**

**Valid till: 27 May 2024**

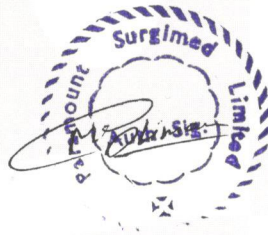
**For PARAMOUNT SURGIMED LIMITED**

Sign & date of issue: 26.07.2021

Name: Manoj Dhiman

Position: Manager QA

Employee code: PS017



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