



# PARAMOUNT SURGIMED LIMITED

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CIN. : U74899DL1993PLC055981

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## 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>Surgical Blades in Carbon Steel and Stainless Steel (Brand-Paramount)</b>	Rule 6, Annex IX	Ila	Sterile by Gamma Irradiation	1, 2, 3, 4, 5, 6, 8, 9, 10, 10A, 11,11K, 12, 13, 14, 15, 15B, 15C, 15D, 15S, 16, 17,18, 19, 20, 21, 22, 22A,23, 24,25, 36, 40, 40B, 60,60B,1R, 2R, 3R, 1V, 2V, 3V, 11P, 12D,24D, 34,36D	XXXXX X	XXXX/X X	XXXX/XX

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 Ila, 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 GL PRESAFE AS,**

Veritasveien 3, N-1363 Høvik, Norway

E-mail: [info@presafe.com](mailto:info@presafe.com)

Website: [www.presafe.com](http://www.presafe.com)

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:

Name: Ajay Dhasmana

Position: Manager QA

Employee code: PS020

18.09.2020



CE 2460



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)