



PARAMOUNT SURGIMED LIMITED

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 CIN. : U74899DL1993PLC055981

Ref. No.: PSL-DOC/V-7/ ISSUE No. 06/ Rev-04, Dated-16-09-2020

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					
Biopsy Punch in Stainless Steel (Brand- Paramount)	Rule 6, Annex IX	Ila	Sterile by Gamma Irradiation	1mm, 1.5mm, 2mm, 2.5mm, 3mm, 3.5mm, 4mm, 5mm, 6mm, 7mm, 8mm	xxxxxx	xxxx/xx	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 'DNV₂₄₆₀' 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 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, 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

Website: www.presafe.com

NOTIFIED BODY NO: 2460



MDSS GmbH, Schiffgraben 41,
D-30175, Hannover, Germany
Email: 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



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)