Ref. No.: PSL-DOC/V-7A/ ISSUE No. 06/ Rev-05, 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					
Biopsy Punch (Brand- Paramount)	Rule 6, Annex IX	IIa	Sterile by Gamma Irradiation	*	*	*	*

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$_{2460}$' 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,

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

CE 2460

NOTIFIED BODY NO: 2460

EC REP
MDSS GmbH, Schiffgraben 41,
D-30175 Hannover, Germany
Tel. +49 511 6262 8630, Email: info@mdss.com

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: 19.10.2022
Name: Manoj Dhiman
Position: Manager QA
Employee code: PS020

* The batch no. model no. mfg. date and exp. date will be included during issue of the doc to the customer.