



PARAMOUNT SURGIMED LIMITED

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 CIN. : U74899DL1993PLC055981

Ref. No.: PSL-DOC/V-8/ISSUE-06/Rev-02, 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 | | | | | |
| Dermal Curette in Stainless Steel (Brand- Paramount) | Rule 6, Annex IX | Ila | Sterile by Gamma Irradiation | 2 mm, 3 mm, 4mm, 5mm 7mm | xxxxxxx | 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 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 '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 ISO 11138-2 :2009

Non- Harmonized- 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, 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



EC REP 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: 18.09.2020
 Name: Ajay Dhasmana
 Position: Manager QA
 Employee code: PS020

