



# TECHNICAL CONSTRUCTION FILE (PSL/TCF/01)

Issue No. 06  
Issue Date: 01-04-19  
Rev.08  
Date: 14/10/2024

**PARAMOUNT SURGIMED LIMITED**  
A-106, RIICO Industrial Area, Bhiwadi -  
301019, District –Alwar, Rajasthan, India

**Title: EC Declaration of Conformity**

Section No.: 15-1  
Page 1 of 1

**Ref. No.: PSL-DOC/V-1A/ISSUE-06/Rev-08, Dated-14-10-2024**

According to annex –II excluding section IV of the MDD 93/42/EEC & by amended directive 2007/47/EC & Article 120 of MDR (EU) 2017/745 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 &amp; stainless Steel (Brand- Paramount)</b>	Rule 6, Annex IX	IIa	Sterile by Gamma Irradiation	*	*	*	*

Meets the provisions of the MDD 93/42/EEC & by amended directive 2007/47/EC & Article 120 of MDR (EU) 2017/745 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.

The following standards were used to prove the products conformity with the essential requirements of the Directive:

**Harmonized** EN ISO 14971: 2019, BS EN ISO 7153-1:2001/BS 5194-1:1991, EN 27740: 1992 (ISO 7740), EN 62366:2008, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-12:2021, EN ISO 10993-23:2021, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015, EN 868-5:2018, EN 556-1:2001/AC:2006, EN ISO 11140-1:2009, EN ISO 13485:2016/A11:2021, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 15223-1:2021

**Non- Harmonized-** BS 2982:1992, ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-3:2019, ISO 14644-4:2022, ISO 14644-5:2004, ISO 2859-1:1999/ AMD 2011, ISO 780:2015, ISO 2247:2000, ISO 14698 -1: 2003, ISO 14698 -2: 2003, ISO 20417: 2021, ISO 6507-1:2018, ISO 11737-3:2023

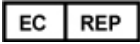
Signatory established within the EU who has been empowered to enter commitments on our behalf:

### NOTIFIED BODY:

**DNV Product Assurance AS, Veritasveien 1, N-1363 Høvik,  
Post Box 161, N-1300, Sandvika, Norway Phone:+47 67578800**

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

**NOTIFIED BODY NO: 2460**

 MDSS GmbH, Schiffgraben 41,  
D-30175 Hannover, Germany  
Tel. +49 511 6262 8630, Email: [info@mdssar.com](mailto:info@mdssar.com)

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

**Date of Issue: 15.09.2020**

**Valid till: 31 December 2028; extended as per Notified Body Confirmation Letter Reference: C684827**

**For PARAMOUNT SURGIMED LIMITED**

Sign & date of issue: 14-10-2024

Name: Meghana

Position: Manager QARA

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