F 8.2.4-18 Rev 8

# CE Certificate of Conformity

JAI SURGICALS LIMITED

H.O. : B-3, Infocity Sector 33-34
Gurgaon 122001, Gurgaon, India

Works: SP(146)L RICCO, Industrial Area
Bhiwadi 301019, Rajasthan, India
Voice : +91 124 433 8888
E-mail : surgeon@jaisurgicals.com
Web : www.jaisurgicals.com

CUSTOMER NAME

**DEROM DENTAL INTERNATIONAL SRL**

PROF. INCULET NO. 3 STREET, 700720 - LASI, ROMANIA

| EOC NO. | INVOICE NO. | P.O NO. | L/C No. | Date |
|---|---|---|---|---|
| 11044 | 277 | Email dtd.16/01/2023 | | |

**LOT No(s) :** 23046346, 23069726

**Expiry Dates (s):** 31/12/2027, 31/01/2028

**Product Description :**

| | |
|---|---|
| Sterile Surgical Blades made of high carbon steel (containing carbon 0.6% & above by weight) duly packed in aluminium foil and sterilised by Gamma Radiation at minimum dosages of 2.5 Mega Rads. FDA Device Listing # E373315. | Total: **1000** Unit Box of 100 pcs . each |
| PRIMA Standard Sterile Disposable Scalpels with stainless steel blade and blade guard. Packed in paper/poly & sterilized by Gamma Radiation at minimum dosage of 2.5 Mega Rads. | Total: **1000** Unit Box of 10 pcs . each |

We **Jai Surgicals Limited**, at B3 Infocity, Sector 33-34, Gurgaon 122001, India, in accordance with the European Medical Device Directive 93/42/EEC do hereby declare that the above products conform to specifications and is in compliance with harmonized standards BS 2982:1992, ISO 7153-1, EN 27740:1992/A1:1997, ISO 7740: 1985, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006/AC2009, BS EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-11:2018, EN ISO 11137-1&2:2015, ISO 15223-1:2016 and those standards specified in its Quality System.

The company has selected TUV SUD, as Notified Body and authorizes the Notified Body to carry out necessary inspection and agrees to supply the required information and data/documents from time to time. CE Certificate Number G1 1056548002 & G1S 1056548003 Rev 00.

The Quality Management System of Jai Surgicals Ltd., is certified by TUV SUD as (Notified Body No. 0123) for design, production and final product inspection/testing of Disposable Medical Devices and hase been assessed with respect to the conformity assessment procedures described in article 11.3.a and Annex II, exluding section 4 of the Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply.

The company agrees to make available all document and data to national authority for a period ending at least seven (7) years after the last product has been manufactured.

The company and its authorized representative Advena Ltd, Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta. shall fulfill the obligations imposed by MDD and ensure and declare that the company's products shall meet all provisions of the directive as applicable.

The company undertakes to keep up to date a systematic procedure to review experiences gained during post production phase and to implement through appropriate means necessary corrective and preventive action taking into account the nature and risk in relation to the product.

The company undertakes to notify immediately any malfunction/deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.

CE 0123 STERILE R +5°C +45°C

EC REP **Advena Ltd.**
Tower Business Centre, 2nd Flr.
Tower Street, Swatar,
BKR 4013, Malta.

For and on behalf of Jai Surgicals Limited

Ambuj Srivastav (General Manager QA/RA)

Dated : **09/03/2023**