



EC Certificate Full Quality Assurance System

Certificate No.:
11315-2017-CE-IND-NA-PS Rev. 1.0

Project No.:
PRJC-243400-2010-PRC-IND

Valid Until:
26 October 2020

This is to certify that the quality system of:

JAI SURGICALS LIMITED

B-3, Infocity, Sector 33-34, Gurgaon -122 001,
Haryana, India.

For design, production and final product inspection/testing of:

Disposable Surgical Blades and Scalpels

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II
excluding section 4 of Council Directive 93/42/EEC on Medical
Devices, as amended**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 03 June 2019



For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB 0434) Certificate no: 7802-2016-CE-IND-NA Rev. 3.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	14-11-2017
1.0	EU Representative Changed	03-06-2019

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical Blades (Sterile & Non Sterile) in Carbon Steel & Stainless Steel	Sizes: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 10B, 10S, 10DP, 11,11B, 11K, 11N, 11PA, 11P, 12, 12A, 12B, 12D, 13,14, 15, 15A, 15B, 15C, 15S, 15T, 15D, 16, 17, 18, 19, 20, 21, 21D, 22, 22A, 22D, 23, 23D, 24, 24D, 25, 25A, 27, 34, 36, 36D, 60, 70, 10SF, 15SF, 18SF, 19SF, 20SF, 21SF, 22SF, 23SF, 24SF, 36SF, 10DM, 11DM, 12DM, 12BDM, 15DM,15CDM, 18DM,19DM, 20DM, 21DM, 22DM, 23DM, 24DM, 25DM, 36DM, 60DM, 10DS, 15DS, 18DS, 19DS, 20DS, 21DS, 22DS, 23DS, 24DS, 36DS, 10OP, 11OP, 12OP, 12BOP, 15OP, 15COP, 18OP, 19OP, 20OP, 21OP, 22OP, 23OP, 24OP, 36OP, 60OP.	Ila
Surgical Blades (Gouge & Curette Type Sterile & Non Sterile) in Carbon Steel & Stainless Steel	Size: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 15, 32, 34, 36	Ila
Disposable Scalpels (Sterile & Non Sterile) in Stainless Steel (Standard , Prima Std./Premium, Prima/Premium Reinforced, Long Premium	Sizes: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 10B, 10S, 10DP, 11,11B, 11K, 11N, 11PA, 11P, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T, 15D, 16, 17, 18, 19, 20, 21, 21D, 22, 22A, 22D, 23, 23D, 24, 24D, 25, 25A, 27, 34, 36, 36D, 60, 70, 10SF, 15SF, 18SF,19SF, 20SF, 21SF, 22SF, 23SF, 24SF, 36SF,10DM, 11DM, 12DM, 12BDM, 15DM,15CDM,18DM, 19DM, 20DM, 21DM, 22DM, 23DM, 24DM, 25DM, 36DM, 60DM, 10DS, 15DS, 18DS, 19DS, 20DS, 21DS, 22DS, 23DS, 24DS, 36DS, 10OP,11OP, 12OP, 12BOP, 15OP, 15COP, 18OP, 19OP, 20OP, 21OP, 22OP, 23OP, 24OP, 36OP, 60OP.	Ila
Retractable Safety Disposable Scalpels (Sterile & Non Sterile) in Stainless Steel with Steadfast Disposal Lock.	Sizes: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10B, 10S, 10DP, 11, 11B, 11K, 11N, 11PA, 11P, 15, 15A, 15B, 15C, 15S, 15T,15D, 16, 17, 18, 19, 20, 21, 21D, 22, 22A, 22D, 23, 23D, 24, 24D, 25, 25A, 27, 34, 36, 36D, 10SF, 15SF, 18SF, 19SF, 20SF, 21SF, 22SF, 23SF, 24SF, 36SF, 10DM, 11DM, 15DM, 15CDM, 18DM, 19DM, 20DM, 21DM, 22DM,	Ila

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	23DM, 24DM, 25DM, 36DM, 10DS, 15DS, 18DS, 19DS, 20DS, 21DS, 22DS, 23DS, 24DS, 36DS, 10OP, 11OP, 15OP, 18OP, 19OP, 20OP, 21OP, 22OP, 23OP, 24OP, 36OP.	
Protective Shield Safety Disposable Scalpels (Sterile & Non Sterile) in Stainless Steel with Steadfast Disposal Lock.	Sizes: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10A, 10B, 10S, 10DP, 11, 11B, 11K, 11N, 11PA, 11P, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T, 15D, 16, 17, 18, 19, 20, 21, 21D, 22, 22A, 22D, 23, 23D, 24, 24D, 25, 25A, 27, 34, 36, 36D, 60, 70, 10SF, 15SF, 18SF, 19SF, 20SF, 21SF, 22SF, 23SF, 24SF, 36SF, 10DM, 11DM, 12DM, 12BDM, 15DM, 15CDM, 18DM, 19DM, 20DM, 21DM, 22DM, 23DM, 24DM, 25DM, 36DM, 60DM, 10DS, 15DS, 18DS, 19DS, 20DS, 21DS, 22DS, 23DS, 24DS, 36DS, 10OP, 11OP, 12OP, 12BOP, 15OP, 15COP, 18OP, 19OP, 20OP, 21OP, 22OP, 23OP, 24OP, 36OP, 60OP.	Ila
Dental Disposable Scalpels (Sterile & Non Sterile) in Stainless Steel.	Sizes: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10B, 10S, 11, 11B, 11K, 11N, 11PA, 11P, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T, 15D, 10SF, 15SF, 10DM, 11DM, 12DM, 12BDM, 15DM, 15CDM, 10DS, 15DS	Ila
Disposable Scalpels (Mini, Thumb) (Sterile & Non Sterile) in Stainless Steel	Sizes : 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 10B, 10S, 11, 11B, 11K, 11N, 11PA, 11P, 12, 12A, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15S, 15T, 15D, 10SF, 15SF, 10DM, 11DM, 12DM, 12BDM, 15DM, 15CDM, 10DS, 15DS	Ila
Stitch Cutter Blades (Sterile & Non sterile) in Carbon Steel & Stainless Steel.	Sizes: Stitch Cutter (SC), Stitch Cutter Long (SCL), Stitch Cutter Medium (SCM), Standard Stitch Cutter (SSC)	Is
Stitch Cutter on a Disposable Handle (Sterile & Non-sterile) with Stainless Steel Blade with Blade guard	Size SC	Is
Safety Stitch Cutter on a Disposable Handle (Sterile & Non-sterile) with Stainless Steel Blade with Steadfast Disposal Lock	Sizes: SC	Is
Skin Graft Blades (Sterile & Non Sterile) in Stainless Steel.	Size: Standard (SGB)	Ila
Sterile Biopsy Punches in Stainless Steel (with and without plunger)	Size: From 0.50 mm to 8.00 mm	Ila
Sterile Heel Incision Device Stainless Steel	Sizes: Depth Length 0.65 mm 1.40 mm 0.85 mm 1.75 mm 1.00 mm 2.5 mm 2.00 mm 3.00 mm	Ila
Sterile Scalpel Blade Handle in Stainless Steel	Sizes: 3, 4, 7, 3L, 4L	Is



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The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
JAI SURGICALS LIMITED	SP 146 (L) RIICO Industrial Area, Bhiwadi – 301 019, Alwar, Rajasthan, India. H.O.: B-3 Infocity, Sector 33-34, Gurgaon,-122 001, Haryana, India.

EU Representative

Advena Ltd., Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta.

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate