



mdc medical device certification GmbH · Kriegerstr. 6 · 70191 Stuttgart, Germany

Tekno-Medical Optik-Chirurgie GmbH
Herrn Florian Mattes
Sattlerstraße 11
78532 Tuttlingen
Deutschland

Your sign, your letter dated

Our sign, our letter dated
OPU-ITH

Phone number
+49 7461 919996-243

Date
2023-05-17

Preliminary Confirmation Letter – validity of MDD certificates

Dear Mr. Mattes,

mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany) has for the manufacturer:

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11
78532 Tuttlingen
Deutschland

issued the following certificate in accordance with Directive 93/42/EEC:

Certificate	Certificate registration No.	Certification	Date of issue	Expiry date
21320	D1043500072	EEC 93/42 Annex V,3	2018-07-04	2023-07-04
25346	D1043500081	EEC 93/42 Annex II, without 4	2020-12-04	2023-07-04
25223	D1043500083	EEC 93/42 Annex II, without 4	2021-05-20	2023-07-04

These certificates were valid as of 20 March 2023 and have not been withdrawn afterwards.

In accordance with the requirements of Art. 120 (2), second subparagraph, first sentence of Regulation (EU) 2017/745 on Medical Devices (MDR), last amended by Regulation (EU) 2023/607 the above mentioned certificates shall remain valid until the date set out in Art 120 (3a) MDR.

This confirmation requires that the manufacturer complies with the requirements laid out in Art. 120 (3c) and (3d) MDR and will undergo further surveillance according to the rules of mdc medical device certification GmbH.

According to the requirements of Art. 120 (3a) MDR, the prerequisite for placing the concerned devices on the market is fulfilled until at least 26 May 2024, unless otherwise specified by the authorities or this letter is replaced by a contrary notification by mdc.

Kind regards,

mdc medical device certification GmbH


i. A. Oliver Puhle
(Project Management)

Seite 1 von 1

ID: 10727-00204.2023
mdc medical device certification GmbH
Kriegerstraße 6
70191 Stuttgart, Germany

Phone +49 711 253567-0
Fax +49 711 253567-10
e-Mail mdc@mdc-cs.de
Web www.mdc-cs.de

General Manager
Chairman of the board
Registered office of the company
UStIDN: DE812189576

Herald Rentchler
Dirk Palige
Stuttgart
AG Stuttgart HRB 21357

15/05/2024

To whom it may concern,

With this official statement the company Asa Dental S.p.A. is willing to declare the exact correspondence between equal instruments from different producers that has at disposal for marketing in its own portfolio:

1, *Equivalence Tab.*

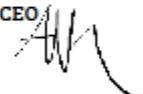
Item Description	Asa Dental	Derby	JAI SURGICALS		TEKNO MEDICAL	
	REF	REF	REF	MADE IN	REF	MADE IN
Steril Carbonsteel surg.blade 100/box	0351-10	DD391-10	04446	INDIA	7210-10T	GERMANY
Steril Carbonsteel surg.blade 100/box	0351-11	DD391-11	04447	INDIA	7210-11T	GERMANY
Steril Carbonsteel surg.blade 100/box	0351-12	DD391-12	04448	INDIA	7210-12T	GERMANY
Steril Carbonsteel surg.blade 100/box	0351-12D	DD391-12D	04449	INDIA	7210-12DT	GERMANY
Steril Carbonsteel surg.blade 100/box	0351-15	DD391-15	04450	INDIA	7210-15T	GERMANY
Steril Carbonsteel surg.blade 100/box	0351-15C	DD391-15C	04451	INDIA	7210-15CT	GERMANY
Steril Carbonsteel surg.blade 100/box	0361-20	-	04454	INDIA	7210-20T	GERMANY
Steril Carbonsteel surg.blade 100/box	0361-21	-	04455	INDIA	7210-21T	GERMANY
Steril Carbonsteel surg.blade 100/box	0361-22	-	04456	INDIA	7210-22T	GERMANY
Steril Carbonsteel surg.blade 100/box	0361-23	-	04457	INDIA	7210-23T	GERMANY
Steril Carbonsteel surg.blade 100/box	0361-24	-	04458	INDIA	7210-24T	GERMANY
Steril Disp.Scalpels 10/box	0371-10	DD397-10	0248	INDIA	-	GERMANY
Steril Disp.Scalpels 10/box	0371-11	DD397-11	0251	INDIA	-	GERMANY
Steril Disp.Scalpels 10/box	0371-12	DD397-12	0254	INDIA	-	GERMANY
Steril Disp.Scalpels 10/box	0371-15	DD397-15	0256	INDIA	-	GERMANY

With Regards

Bozzano,

Alessandro Malfatti

Asa Dental CEO



EXPORT DIVISION:
STABILIMENTI/PLANTS:

Tel. +39 0584 938304
Via Sorzanese Valdora, 1151 - Bozzano - 55054 Massarosa (Lu)
Via delle Piagge, 1/A - Marito - 55014 Capannori (Lu)
Via Fierla, 13 - Z.I. - 33083 Montebelluna (Tv)

BANCHE/BANKS:

Deutsche Bank Viareggio - IBAN: IT 21 A 02104 13700 00000010733
Intesa San Paolo SpA Viareggio - IBAN: IT 20 E 06260 24803 00000010326
Monte Dei Paschi di Siena Viareggio - IBAN: IT 64 A 01050 24800 000063305758

Cap. Sociale € 268.580,00 i.v. - PIVA (VAT IT) 00525990461 - R.E.A. LU 104357 - C.C.I.A.A. Lucca n. 00525990461 - Esp. M. LU 007444





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
EU Declaration of Conformity

F 8.2.4-18A
Rev - 02

Date: 26/05/2022

Declaration of Conformity

For Product Name –

1. Surgical Blades (Sterile & Non-sterile) in Carbon Steel & Stainless Steel.
2. Disposable Scalpels (Sterile & Non-sterile) Surgical blades fitted on Disposable handle with blade Guard
3. Retractable Safety Disposable Scalpels (Sterile & Non-sterile) in Stainless Steel with Steadfast Disposal Lock.
4. Protective Shield Safety Disposable Scalpels (Sterile & Non-sterile) in Stainless Steel with Steadfast Disposal Lock.
5. Dermal Curette (Sterile & Non Sterile) in Stainless steel,
6. Sterile Biopsy punches in stainless steel (with and without plunger).

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Surgical blades and scalpels
Legal Manufacturer: (Name on Label)	JAI SURGICALS LIMITED, B-3, Infocity, Sector 33-34, Gurgaon – 122 001, Haryana, India
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Surgical Incision, Cutting, Scraping
MD Directive Classification:	Class IIa
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstr,65,80339 Munich , Germany (Notified Body No. 0123)
CE Certificate	Certificate No. G1 105648 0002 Rev.00, Valid up to 26.05.2024
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	EC Declaration by the Notified Body to Annex II of the Medical Device Directive

Name Ambuj Srivastav Position General Manager –QA/BA & MR

Signed  Date 26/05/2022

Konformitätserklärung*Dichiarazione di Conformità*

im Sinne der Richtlinie 93/42 EWG: Anhang II, ohne Abschnitt 4
ai sensi di Medical Device Directive 93/42 /CEE: allegato II, senza sezione 4

Wir, die Firma **Tekno – Medical**
Noi, la ditta **Sattlerstr. 11**
 78532 Tuttlingen

erklären in alleiniger Verantwortung, dass folgende Produktgruppe
di chiariamo sotto la nostra sola responsabilità, che i seguenti prodotti del gruppo

Medizinprodukte
Dispositivi medici

UMDNS: **siehe Anhang Produktliste zur Konformitätserklärung**
UMDNS: *vd. allegato lista di prodotti Dichiarazione di Conformità*

Klassifizierung nach 93/42/EWG nach Anhang IX:
siehe Anhang Produktliste zur Konformitätserklärung
Classificazione ai sensi di 93/42/CEE allegato IX:
vd. allegato lista di prodotti Dichiarazione di Conformità

allen Anforderungen der Richtlinie 93/42/EWG, zuletzt geändert durch die EU-Richtlinie
2007/47EG entsprechen.
Corrispondono a tutte le richieste della direttiva 93/42/CEE, ultimamente cambiata con la direttiva 2007/47/CE.

Zusätzliche Angaben / informazioni addizionali:

Die Entwicklung, Herstellung und der Vertrieb der Produkte wird durch ein QM-System gemäß
den Forderungen der ISO 13485, des Medizinproduktegesetzes und der FDA unterstützt.
La progettazione, fabbricazione e distribuzione dei prodotti è supportata da un sistema qualità secondo le richieste della ISO 13485, della legge dei dispositivi medici e della FDA.

Das QM-System wird überwacht durch die Benannte Stelle 0483
mdc medical device certification GmbH, Kriegerstr. 6, D-70191 Stuttgart, Germany.
Il sistema di qualità viene controllato dall'organismo notificato 0483
mdc medical device certification GmbH, Kriegerstr. 6, D-70191 Stuttgart, Germany.

gültig bis: **04.07.2023**
valido fino a:

Ort: **Tuttlingen**

Luogo:

Datum: **26.05.2021**

Data:



TEKNO
TEKNO MEDICAL
Optik-Chirurgie GmbH
Sattlerstr. 11
78532 Tuttlingen, Germany
Phone: +49 7141 12 01-0
Fax: +49 7141 12 01-50
www.tekno-medical.com

Ulrich Spaett
Person Responsible
for Regulatory Compliance



JAI SURGICALS LIMITED

B-3 Infocity, Sector 33-34, Gurgaon-122 001, Haryana, India
Tel : +91-124-433 8888 Fax : +91-124-433 8800
e-mail : surgeon@jaisurgicals.com
www.jaisurgicals.com

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	JAI SURGICALS LIMITED
Manufacturer address and contact details	B-3, INFOCITY SECTOR 33-34 GURGAON, HARYANA 122001 INDIA
Single Registration Number (SRN) (if available)	IN-MF-000012813

Authorised Representative name (if applicable)	ADVENA LIMITED
Authorised Representative address and contact details	TOWER BUSINESS CENTRE 2 ND FLR TOWER STREET SWATAR BKR 4013 MALTA
Single Registration Number (SRN) (if available)	MT-AR-000000234

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Jai Surgicals Ltd,
SP-146 (L),
RIICO Industrial Area Distt. Alwar,
Bhiwadi, Rajasthan, 301019 ,
India

26 May 2024

Notified Body Confirmation Letter
Reference: CN00513-01-01

To whom it may concern,

Certificates included:

MDD EC Certificate Annex II, G1S 105648 0003 Rev.00 (NB0123)

MDD EC Certificate Annex II, G1S 105648 0002 Rev.00 (NB0123)

See attached tables for details of devices.

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Jai Surgicals Ltd,
SP-146 (L),
RIICO Industrial Area Distt. Alwar,
Bhiwadi, Rajasthan, 301019 ,
India

SRN Number (if available): IN-MF-000012813

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate