EC CERTIFICATE

Certificate No 1826/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

TSUNAMI MEDICAL S.R.L.

41124 MODENA (MO) - VIA EMILIO GIORGI 27 (ITA) - Italy

manages in the factory of:

41037 MIRANDOLA (MO) - VIA XXV APRILE 22 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Intervertebral arthrodesis systems

Interspinous fusion system

Percutaneous discectomy device

Ciphoplastic, verthebroplastic devices and accessories

Needles and biopsy sets

Devices for percutaneous discectectomy

Sclerotherapy devices

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AO00218; DM15A0482846-01; DM15G0476904-01; DM15S0502491-01; DM16A0587769-01; DM16A0655593-01; DM16-0003320-01; DM17-0010609; DM16-0007367-01; DM18-0026818-01; DM18-0029861-01; DM18-0032045-01; DM19-0041866-01; DM19-0042300-01; DM19-0038088-01; DM20-0047699-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2015-11-03
Updated:	2020-05-25
Substitution Date:	2020-03-09
Expiry Date:	2024-05-26

DocuSign

IMQ

DOVA, mun.CHIŞINAU, SOCIETATEA CU RASPUNDERE LIMITATA - REPUBLICA S.R.L. «NEUROKOS» IDNO 1007600020455

EC CERTIFICATE

Certificate No 1826/MDD

Annex

Intervertebral arthrodesis systems

Type ref. As to attached document "FT10 - Cage per artrodesi Cap. 04 Elenco Codici" Rev. 01 dated 2018/03/27; valid only if provided with IMQ stamp.

Interspinous fusion system

Type ref. As to attached document "FT14: INTERSPINOUS FUSION SYSTEM" Rev. 02 dated 2018/06/20; valid only if provided with IMQ stamp.

Percutaneous discectomy device

Type ref. as to attached document "FT03: Percutaneous discectomy device" Rev. 02 dated 2018/09/03; valid only if provided with IMQ stamp.

Ciphoplastic, verthebroplastic devices and accessories

Type ref. As to attached document "FT05: Ciphoplastic, verthebroplastic devices and accessories - Elenco Codici" Rev. 02 dated 2019/01/02; valid only if provided with IMQ stamp.

Needles and biopsy sets

Type ref. As to attached document "FT01: Needles and biopsy set" Rev. 02 dated 2020/05/13; valid only if provided with IMQ stamp.

Devices for percutaneous discectectomy

Type ref. As to attached document "FT11: Percutaneous discectomy device - discolux - Codes list" Rev. 01 dated 2020/05/13; valid only if provided with IMQ stamp.

Sclerotherapy devices

Type ref. As to attached document "FT16: Sclerotherapy device Cap. 4 Codes List" Rev. 01 dated 2020/05/13; valid only if provided with IMQ stamp.

Date:	2015-11-03
Updated:	2020-05-25
Substitution Date:	2020-03-09
Expiry Date:	2024-05-26

DocuSign

IMQ

S.R.L. «NEUROKOS»

This is a translation of the Italian text, which prevails in case of doubts

TSUNAMI S.R.L.
Via XXV Aprile, 22
41037 - Mirandola (MO) - ITALY
tel. +39 0535 38397 / fax +39 0535 38399
tsunamimedical.info@me.com
www.tsunamimedical.it

ALLEGATO TECNICO ALLA DICHIARAZIONE DI CONFORMITÀ CE NO.
TECHNICAL ANNEX TO CE DECLARATION NO.

Il presente documento è parte integrante della dichiarazione di conformità CE
Present document is an integral part of CE Declaration

5

FAMIGLIA / CODE	DESCRIZIONE	DESCRIPTION
DAVxx/yy[D][T]	DAV - Kit per vertebroplastica doppio accesso	DAV - Double access vertebroplasty kit
DAVxx/yyH[D][L][T]	DAV H - Kit per vertebroplastica doppio accesso con siringa idraulica	DAV H - Double access vertebroplasty kit with hydraulic syringe
DAVSxx/yy[D][T]	DAVS - Kit per vertebroplastica doppio accesso con siringa a vite	DAVS - Double access vertebroplasty kit with screw syringe
DHSxx/yy[D][T]	DHS - Kit per vertebroplastica doppio accesso con cannula istologica antilussazione	DHS - Double access vertebroplasty kit with antiluxation histological cannula
DHSxx/yyH[D][L][T]	DHS H - Kit per vertebroplastica doppio accesso con cannula istologica antilussazione e con siringa idraulica	DHS H - Double access vertebroplasty kit with antiluxation histological cannula and with hydraulic syringe
DHSSxx/yy[D][T]	DHSS - Kit per vertebroplastica doppio accesso con cannula istologica antilussazione e siringa a vite	DHSS - Double access vertebroplasty kit with antiluxation histological cannula and screw syringe
SAVxx/yy[D][T]	SAV - Kit per vertebroplastica singolo accesso	SAV - Single access vertebroplasty kit
SAVxx/yyH[D][L][T]	SAV H - Kit per vertebroplastica accesso singolo con siringa idraulica	SAV H - Single access vertebroplasty kit with hydraulic syringe
SAVSxx/yy[D][T]	SAVS - Kit per vertebroplastica accesso singolo con siringa a vite	SAVS - Single access vertebroplasty kit and screw syringe
VMxx/yy[D][T]	VM - Kit da vertebroplastica con sistema di miscelazione ed iniezione	VM - Vertebroplasty kit with mixing and injection system
VM2xx/yy[D][T]	VM2 - Kit da vertebroplastica per accesso doppio con sistema di miscelazione ed iniezione	VM2 - Vertebroplasty kit double access with mixing and injection system
SHP	Siringa a vite per iniezione cemento	Cement injection screw syringe
VERTEBROxx/yy	Ago per accesso osseo	Bone access needle
BBLVxx/yy[D][HF][T]	Ago per accesso osseo	Bone access needle
NBAxx/yy	Ago da navigazione per accesso osse	Navigated bone access needle

FIRMA QA/RA SIGN QA/RA	FIRMA GM SIGN GM

TSUNAMI S.R.L.
Via XXV Aprile, 22
41037 - Mirandola (MO) - ITALY
tel. +39 0535 38397 / fax +39 0535 38399
tsunamimedical.info@me.com
www.tsunamimedical.it

ALLEGATO TECNICO ALLA DICHIARAZIONE DI CONFORMITÀ CE NO.
TECHNICAL ANNEX TO CE DECLARATION NO.

Il presente documento è parte integrante della dichiarazione di conformità CE
Present document is an integral part of CE Declaration

5

FAMIGLIA / CODE	DESCRIZIONE	DESCRIPTION
ASNzz	Siringa per iniezioni di cemento	Cement injection syringe
TVNxx/yy[HF][T] PN 79770 Rev A	Ago guida per accesso osseo con punta diamante e punta a becco di flauto	Targeting needle, 11G x 15cm, Double Diamont and Bevel Point
SHP	Siringa a vite per iniezioni di cemento	Cement injection screw syringe

LEGENDA

xx = Gauge (diametro) / Gauge (diameter)

yy = lunghezza / length

cc = centimetri cubici / cubic centimeters

HF = impugnatura HF ergonomica / ergonomic "HF" handle

A = modello avanzato / advanced model

T = impugnatura a T tipo "Twist" / "Twist" handle

D = con ago di accesso a punta diamantata / with access needle with diamond tip

L = in kit con prolunga da mt. 1,5 / in kit with mt. 1,5 connection tube

[ ] = opzionale / optional

FIRMA QA/RA SIGN QA/RA	FIRMA GM SIGN GM

www.imq.it

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. / *CERTIFICATE N.* 9124.TSNM

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

TSUNAMI MEDICAL S.R.L.

VIA E. GIORGI 27 - 41124 MODENA (MO)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA XXV APRILE 22 - 41037 MIRANDOLA (MO)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e fabbricazione di aghi e set per sistemi automatici e manuali per biopsia, aghi e set per applicazioni diagnostiche, kit per cifoplastica e vertebroplastica e relativi accessori, impianti spinali
Design and manufacture of needles and set for automatic and manual biopsy systems, needles and sets for diagnostic applications, kit for kyphoplasty and vertebroplasty and related accessories, spinal implants

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2009-12-02	2020-05-20	2021-12-01

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

IMQ
Organismo di Certificazione Federato CISQ
www.imq.it

CISQ
FEDERAZIONE
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.