ITALCERT

CERTIFICATO 460-00-01-DM
CERTIFICATE 460-00-01-DM

ITALCERT S.r.l.

certifica che il
certifies that the

Sistema Completo di Garanzia della Qualità messo in atto
per la progettazione, la fabbricazione ed il controllo finale di Dispositivi Medici
Production Quality Assurance System applied
for the design, manufacture and final inspection of Medical Devices

dal Fabbricante
by the Manufacturer

PROSIMED S.r.l.

Via della Magliana, 295 – 00146 ROMA (RM) – ITALIA

nella sede operativa di
in the headquarter located in

Via della Magliana, 295 – 00146 ROMA (RM) – ITALIA

è conforme ai requisiti previsti dalla
complies with the requirements stated in

Direttiva 93/42/CEE - Allegato II (con esclusione del punto 4)
Directive 93/42/EEC - Annex II (excluding point 4)

ed autorizza lo stesso fabbricante ad apporre la marcatura
and authorizes the manufacturer to mark

CE 0426

in accordo ai criteri previsti dall'All. XII della Direttiva 93/42/CEE
sui DM riportati nell'Allegato 1 del presente Certificato
in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
the MD reported in Annex 1 of this Certificate

Dr. Ing. Roberto Cusolito
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Data di rilascio	Emissione Corrente	Data di scadenza
First Issue Date	*Current Emission*	*Expire Date*
2020-03-16	2020-10-21	2024-05-26

Il presente Certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato I
This certificate must be published only in integral form and accompanied by its Annex 1

ITALCERT S.r.l. | Organismo Notificato n° 0426 | Viale Sarca, 336 – 20126 Milano (MI)
tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

ITALCERT

Allegato 1 al Certificato 460-00-01-DM
Annex 1 to Certificate 460-00-01-DM

DISPOSITIVI MEDICI IMPIANTABILI PER ORTOPEDIA
IMPLANTABLE ORTHOPAEDICS MEDICAL DEVICES

VITE PER PIEDE PIATTO A DOPPIA ESPANSIONE (DISTALE E PROSSIMALE) – classe IIb
DOUBLE EXPANSION FLAT FOOT SCREW (DISTAL AND PROXIMAL) – class IIb

Codice / *code*	**Descrizione** / *description*
41-0915	Vite per piede piatto a doppia espansione Ø9x18 mm / *Double expansion flat foot screw Ø9x18 mm*

VITE ENDOSENOTARSICA PER LA CORREZIONE DEL PIEDE PIATTO - Mod. Mid-Lock – classe IIb
SUBTALAR SCREW FOR FLAT FOOT CORRECTION - Mod. Mid-Lock – class IIb

Codice / *code*	**Descrizione** / *description*
ML-0713	Vite endosenotarsica Ø7 x 13 mm / *Subtalar Screw Ø7 x 13 mm*
ML-0814	Vite endosenotarsica Ø8 x 14 mm / *Subtalar Screw Ø8 x 14 mm*
ML-0915	Vite endosenotarsica Ø9 x 15 mm / *Subtalar Screw Ø9 x 15 mm*
ML-1016	Vite endosenotarsica Ø10 x 16 mm / *Subtalar Screw Ø10 x 16 mm*
ML-1117	Vite endosenotarsica Ø11 x 17 mm / *Subtalar Screw Ø11 x 17 mm*
ML-1218	Vite endosenotarsica Ø12 x 18 mm / *Subtalar Screw Ø12 x 18 mm*

VITE ENDOSENOTARSICA PER LA CORREZIONE DEL PIEDE PIATTO - Mod. Jack S – classe IIb
SUBTALAR SCREW FOR FLAT FOOT CORRECTION - Mod. Jack S – class IIb

Codice / *code*	**Descrizione** / *description*
42-0712	Vite endosenotarsica Ø7 x 12 mm / *Subtalar Screw Ø7 x 12 mm*
42-0814	Vite endosenotarsica Ø8 x 14 mm / *Subtalar Screw Ø8 x 14 mm*
42-0914	Vite endosenotarsica Ø9 x 14 mm / *Subtalar Screw Ø9 x 14 mm*
42-1014	Vite endosenotarsica Ø10 x 14 mm / *Subtalar Screw Ø10 x 14 mm*
42-1116	Vite endosenotarsica Ø11 x 16 mm / *Subtalar Screw Ø11 x 16 mm*
42-1216	Vite endosenotarsica Ø12 x 16 mm / *Subtalar Screw Ø12 x 16 mm*

VITE PER PIEDE PIATTO AD ESPANSIONE – classe IIb
EXPANSION FLAT FOOT SCREW – class IIb

Codice / *code*	**Descrizione** / *description*
40-0007	Vite per piede piatto ad espansione Ø7 x 12mm / *Expansion flat foot screw Ø7 x 12mm*
40-0009	Vite per piede piatto ad espansione Ø9 x 12mm / *Expansion flat foot screw Ø9 x 12mm*
40-0011	Vite per piede piatto ad espansione Ø11 x 12mm / *Expansion flat foot screw Ø11 x 12mm*

ITALCERT S.r.l. | Organismo Notificato n° 0426 | Viale Sarca, 336 – 20126 Milano (MI)
tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

Allegato 1 al Certificato 460-00-01-DM
Annex 1 to Certificate 460-00-01-DM

FILI GUIDA – classe IIb
GUIDE WIRES – class IIb

Codice / *code*	**Descrizione** / *description*
62-1200	Filo guida Inox Ø1.2 / *Inox guide wire Ø1.2*
62-1500	Filo guida Inox Ø1.5 / *Inox guide wire Ø1.5*
62-2000	Filo guida Inox Ø2 / *Inox guide wire Ø2*
62-2500	Filo guida Inox Ø2.5 / *Inox guide wire Ø2.5*
62-3000	Filo guida Inox Ø3 / *Inox guide wire Ø3*
62-3500	Filo guida Inox Ø3.5 / *Inox guide wire Ø3.5*
62-4000	Filo guida Inox Ø4 / *Inox guide wire Ø4*
64-1528	Filo guida titanio Ø1.5 / *Titanium guide wire Ø1.5*
64-2028	Filo guida titanio Ø2 / *Titanium guide wire Ø2*
64-2528	Filo guida titanio Ø2.5 / *Titanium guide wire Ø2.5*
64-3028	Filo guida titanio Ø3 / *Titanium guide wire Ø3*
64-4028	Filo guida titanio Ø4 / *Titanium guide wire Ø4*

DISPOSITIVI NON ATTIVI PER ORTOPEDIA E RIABILITAZIONE
NON ACTIVE DEVICES FOR ORTHOPEDICS AND REHABILITATION

FISSATORE ESTERNO – classe Is
EXTERNAL FIXATOR – class Is

Codice / *code*	**Descrizione** / *description*
FC-1215	Montaggio INF+SUP Ø1.2 – Ø1.5
FSC-1216	Piastrino superiore in fibra di carbonio per 2 fili da Ø1.2-1.5 *Carbon fiber upper plate for 2 wires Ø1.2-1.5*
FSC-1217	Piastrino inferiore in fibra di carbonio per 2 fili da Ø1.2-1.5 *Bottom plate in carbon fiber for 2 wires Ø1.2-1.5*
FC-2025	Montaggio INF+SUP Ø2- Ø2.5 *INF+SUP mounting Ø2- Ø2.5*
FC-2026	Piastrino superiore in fibra di carbonio per 2 fili da Ø2-2.5 *Upper plate in carbon fiber for 2 wires Ø2-2.5*
FC-2027	Piastrino superiore in fibra di carbonio per 2 fili da Ø2-2.5 *Upper plate in carbon fiber for 2 wires Ø2-2.5*
FC-2540	Montaggio INF+CENT+SUP / *INF+CENT+SUP assembly*
FLC-2531	Piastrino superiore in fibra di carbonio per 4 fili da Ø2.5 a Ø4 *Upper plate in carbon fiber for 4 wires from Ø2.5 to Ø4*
FLC-2532	Piastrino centrale in fibra di carbonio per 4 fili da Ø2.5 a Ø4 *Central plate in carbon fiber for 4 wires from Ø2.5 to Ø4*
FLC-2533	Piastrino inferiore in fibra di carbonio per 4 fili da Ø2.5 a Ø4 *Bottom plate in carbon fiber for 4 wires from Ø2.5 to Ø4*

ITALCERT S.r.l. | Organismo Notificato n° 0426 | Viale Sarca, 336 – 20126 Milano (MI)
tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

ITALCERT

Allegato 1 al Certificato 460-00-01-DM
Annex 1 to Certificate 460-00-01-DM

FISSATORE ESTERNO E FILI GUIDA (CONFEZIONE DI VENDITA) – classe IIb
EXTERNAL PERCUTANEOUS FIXATOR AND GUIDE WIRES FOR FRACTURES OF THE FINGERS – class IIb

Codice / *code*	**Descrizione** / *description*
FCX21215	FC-1215 e 62-1200 - Fixor per Mano in Fibra di Carbonio con 2 fili inox Ø1.2x150 *FC-1215 and 62-1200 - Fixor for Hand, carbon fiber with 2 inox wires Ø1.2x150*
FCX22040	FC-2025 e 62-2000 - Fixor per Polso in Fibra di Carbonio con 2 fili inox Ø2x400 *FC-2025 and 62-2000 - Fixor for wrist, carbon fiber with 2 inox wires Ø2x400*
FCX22540	FC-2025 e 62-2500 - Fixor per Polso in Fibra di Carbonio con 2 fili inox Ø2.5x400 *FC-2025 and 62-2500 - Fixor for wrist, carbon fiber with 2 inox wires Ø2.5x400*
FCX42540	FC-2540 e 62-2500 - Fixor per Omero in Fibra di Carbonio con 2 fili inox Ø2.5x400 *FC-2540 and 62-2500 - Fixor for Homer, carbon fiber with 2 inox wires Ø2.5x400*
FCX43040	FC-2540 e 62-4000 - Fixor per Omero in Fibra di Carbonio con 2 fili inox Ø3x400 *FC-2540 and 62-4000 - Fixor for Homer, carbon fiber with 2 inox wires Ø3x400*

Milano, 2020-10-21

Dr. Ing. Roberto Cusolito
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

ITALCERT S.r.l. | Organismo Notificato n° 0426 | Viale Sarca, 336 – 20126 Milano (MI)
tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

Prosimed S.r.l.
Via della Magliana, 295
00146 Roma (RM) – Italy

2024.12.03

Notified Body Confirmation Letter
Reference: Contract Nr <127118>

To whom it may concern,

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, ICIM SPA, Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 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:

Prosimed srl
Via della Magliana, 295
00146 – Roma (Italia)

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 surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the ICIM has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

ICIM SPA
Piazza Don Enrico Mapelli, 75
20099 Sesto San Giovanni MI
Identification on NANDO CE0425

Table 1: Devices covered by this letter and for which ICIM SPA is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Vacuum Regulators and its accessories	Class IIa	N.A.	Cert. Nr 0425 MED 00373600 NB 0425
Subtalar Screw for flat foot surgery	Class IIb	N.A.	Cert Nr 460-00-01-DM NB 0426
Double/Single Expansion screw for flat foot	Class IIb	N.A.	Cert Nr 460-00-01-DM NB 0426
Guide Wires	Class IIb	N.A.	Cert Nr 460-00-01-DM NB 0426
External Fixators	Is	N.A.	Cert Nr 460-00-01-DM NB 0426

Table 2: Devices covered by this letter and for which ICIM SPA is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

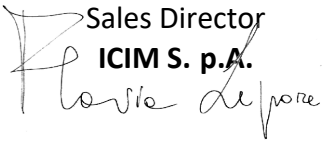
Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.12.03	000127118	Initial issue

Remaining at your disposal for any clarification on the content of this letter, we take this opportunity to extend our best regards.

Edoardo Dossena
Product Sales Manager Product Certification, Inspections and Directives
ICIM S.p.A.

Flavia Lepore
Sales Director
ICIM S. p.A.



1438CM_00_EN