MTIC INTERCERT

CERTIFICATE

CERTIFICATO CE DI APPROVAZIONE DEL SISTEMA COMPLETO DI GARANZIA DI QUALITÁ
FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/414-2021

secondo allegato II della Direttiva 93/42/CEE sui Dispositivi Medici e ss.mm.ii.
according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert dichiara di avere effettuato l'esame del Sistema Completo di Garanzia della Qualità della Società più avanti menzionata seguendo i requisiti della legislazione citata cui essa è soggetta, come da allegato II (esclusa la sezione 4) della Direttiva 93/42/CEE sui Dispositivi Medici. **MTIC Intercert certifica che il Sistema Completo Della Garanzia della Qualità è conforme ai requisiti essenziali della legislazione citata. La validità del presente certificato è soggetta all'esito positivo delle previste visite di sorveglianza.**
MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. ***MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.***

FABBRICANTE:
MANUFACTURER:

MEDICAL DUE S.r.l.

Via Trento, 43 – 37014 Castelnuovo del Garda (VR) – ITALIA

DISPOSITIVO/I:
DEVICE/S:

1. **Chiodi endomidollari in lega di titanio e viti**
   Intramedullary titanium alloy nails and screws
2. **Dispositivo per artrorisi endosenotarsica**
   Sinus tarsi arthroereisis device

MODELLO/I:
MODEL/S:

1. **ENDOLOG (Cod. 1500-044 / 1500-045 / 1500-046 / 1500-415 / 1500-420);**
   ENDOLOG Adapta (Cod. 1500-ADT; 1500-417);
2. **KONE-LOG (Cod. KL-06; KL-07; KL-08; KL-09; KL-10; KL-11; KL-12; KL-13);**

FIRST ISSUE: *FIRST ISSUE*	25/05/2021	EMISSIONE CORRENTE *CURRENT ISSUE:*	25/05/2021	REVISIONE N.: *REVISION Nr.:*	00	DATA SCADENZA: *EXPIRING DATE:*	27/05/2024

Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body

F-PC-DM-14-01-01 Rev.0.1 en

MTIC INTERCERT S.r.l. - Via Moscova, 11 - 20017 RHO (MI) - ITALY
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Declaration of manufacturer

Regarding Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 with respect to transitional arrangements for certain medical devices and in vitro diagnostic medical devices, in particular regarding

- 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

- compliance of the devices and us as their manufacturers with the conditions for continued placing on the market and commissioning.

Manufacturer Name	MedicalDue s.r.l.
Manufacturer address	Via Trento 43, 37014 Castelnuovo del Garda – Verona (VR) Italia
Single registration number (SRN)	IT-MF-000041130

Notified body name	MTIC InterCert S.r.l.
Number of notified body	0068
Number(s) of the certificate of Directive to which this confirmation is made	CE n. 0068/QCO-DM/414-2021
Original expiration date indicated on the directive certificate before the extension of validity	2024-05-27
End date of the period of validity/extended transition	2027-12-31

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

MedicalDue s.r.l., as manufacturer, declares under our sole responsibility that:

- for the certificates in accordance with MDD Directive 93/42/EEC listed above, the conditions for legal extension of validity set forth in Article 120.2 of MDR and/or2 are met

- the devices listed in the attached list and MedicalDue s.r.l., as the legal manufacturer, are in compliance with the conditions set forth in Article 120.3c of the MDR Regulation for continued placing on the market and commissioning,

in particular, meeting the following conditions:

⇒ **CE certificates in accordance with the Medical Device Directive 93/42/ CE stated above and in the attached list**

- MDD 93/42/EEC certificates for devices listed in the annex were issued after May 25, 2017, were valid on May 26, 2021, and were not withdrawn thereafter, expire after March 20, 2023,
- the formal application to the notified body in accordance with Section 4.3, first paragraph of Annex VII MDR for conformity assessment was submitted by MedicalDue s.r.l. for the devices listed in the annex or their substitutes and a written agreement was signed in accordance with Section 4.3, second paragraph of Annex VII MDR before September 26, 2024.

⇒ **Quality management system (QMS)**

A QMS under Article 10(9) MDR will be established by May 27, 2024.n SGQ.

⇒ **Devices listed in the attached program**

- The devices continue to comply with AIMDD or MDD.
- There are no significant changes in design or intended use.
- The devices do not present an unacceptable risk to the health or safety of patients, users or others, or to other aspects of public health protection.

Signed by Manufacturer:

MedicalDue s.r.l. Giuseppe Lodola

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

List of devices

The Manufacturer's Declaration above is valid for the following devices:

Identification of the device(s)3 (e.g., device name, family/group name device model, or catalog number)	**Number(s) of the directive certificate to which this confirmation is made**	**Original expiration date indicated on the directive certificate(s) before the extension of validity**	**Name and number of the notified body that has issued the directive certificate**	**Name and number of the notified body where the MDR/agreement application was submitted signed**	**End date of validity/transition period extended**	**Replacement devices** (if applicable)
Endolog (titanium nail Endolog Ø 4,5 x 40 mm)	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Endolog (titanium nail Endolog Ø 4,5 x 45 mm)	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Endolog (titanium nail Endolog Ø 4,5 x 46 mm)	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Endolog (titanium nail EndologAdapta)	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Endolog (titanium screw Endolog Ø 3,66 mm - lungh. 15 mm)	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Endolog (titanium screw Endolog Ø 3,66 mm - lungh. 17 mm)	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Endolog (titanium screw Endolog Ø 3,66 mm - lungh. 20 mm)	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Sinus tarsi arthroereisis device Kone-Log KL-06	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	

Sinus tarsi arthroereisis device Kone-Log KL-07	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Sinus tarsi arthroereisis device Kone-Log KL-08	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Sinus tarsi arthroereisis device Kone-Log KL-09	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Sinus tarsi arthroereisis device Kone-Log KL-10	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Sinus tarsi arthroereisis device Kone-Log KL-11	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Sinus tarsi arthroereisis device Kone-Log -KL12	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	
Sinus tarsi arthroereisis device Kone-Log KL-13	0068/QCO-DM/414-2021	27/05/2024	MTIC InterCert S.r.l. Via Moscova, 11 - 20017 RHO (MI) - ITALY	ICIM SpA, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY	31/12/2027	

3 for devices with AIMDD/MDD certificate(s), the identification should be as in the certificate and only if the certificate has a generic scope should it be defined as above.

Dichiarazione del fabbricante - storia delle revisioni

Data	Azione
27/05/2024	Initial issue