

DICHIARAZIONE DI CONFORMITÀ UE EU DECLARATION OF CONFORMITY

Fabbricante/ <i>Manufacturer</i>	BIOTEC s.r.l.
Sede legale del fabbricante/ <i>Manufacturer Head Office</i>	Via Industria, 53 - 36031 Povolaro di Dueville (VI) – ITALY Tel: +39.0444.361251 – Email: info@btk.dental
Numero di Registrazione Unico/ <i>Single Registration Number</i>	IT-MF-000026774

Il fabbricante **BIOTEC** dichiara che la presente Dichiarazione di Conformità UE è rilasciata sotto la sua esclusiva responsabilità e si riferisce ai seguenti dispositivi:

/The manufacturer, BIOTEC, declares that this EU Declaration of Conformity is issued under its sole responsibility and is applicable to the following medical devices:

CONNESSIONE MICROMOTORE/ CONNECTION FOR MICRO-ENGINE: PROLUNGA FRESA /DRILL EXTENSION, CHIAVE O DRIVER /WRENCH OR DRIVER

La Società **BIOTEC**, dichiara sotto la propria responsabilità che i dispositivi medici, di cui all' oggetto, sono conformi al Regolamento UE 2017/745 sui dispositivi medici e, se del caso, a qualsiasi altra legislazione pertinente dell'Unione che preveda il rilascio di una dichiarazione di conformità UE.

I states under its own responsibility that these medical devices, to which this declaration relates, comply the essential safety requirements set out in Annex I of EU Regulation 2017/745.

Biotec inoltre dichiara, sotto la propria responsabilità quanto segue:

/Biotec also declares, under its own responsibility, that:

- i dispositivi medici soddisfano i requisiti generali di sicurezza e prestazione di cui all' allegato I del Regolamento UE 2017/745.
/the medical devices comply the general safety and performance requirements set out in Annex I of EU Regulation 2017/745.
- i dispositivi medici hanno classe di rischio IIA, in accordo alla regola 5 dell'allegato VIII del Regolamento UE 2017/745.
/the medical devices have risk class IIA, according to rule 5 Annex VIII of EU Regulation 2017/745.
- i dispositivi medici sono progettati, fabbricati e posti in commercio secondo quanto riportato nel fascicolo tecnico di prodotto (DT10D), nell' ambito dell' applicazione di un sistema completo di garanzia della qualità. Tale fascicolo tecnico è stato dichiarato conforme dall' ente ITALCERT, Organismo notificato ai sensi del Regolamento UE 2017/745 con numero 0426, in conformità a quanto prescritto dall' allegato II del suddetto Regolamento. (Ultimi Certificati emessi: N. 007-00-02-MDR emissione il 27-07-2023 e 008-00-02-MDR emissione il 27-07-2023).
/the medical devices have been designed, manufactured and marketed as reported in the technical dossier (DT10D), following the full quality assurance system. This dossier has been declared compliant by ITALCERT, Notified Body under EU Regulation 2017/745 with number 0426, in accordance with all the requirements of Annex II of that Regulation. (Last Certificates issued N° 007-00-02-MDR, issue 2023-07-27 and 008-00-02-MDR, issue 2023-07-27).
- il sistema qualità adottato per la progettazione e fabbricazione di tutti i dispositivi è conforme alle norme UNI EN ISO 9001 e UNI EN ISO 13485.
/the quality system adopted for the design and manufacture of all devices complies with the UNI EN ISO 9001 and UNI EN ISO 13485 standards.

Di seguito si riporta l'elenco dei dispositivi inclusi nella presente Dichiarazione:

/hereby we report a list of devices included in this Declaration:

Cod. Dispositivo/ Device Code	Descrizione Principale/ Main Description	Descrizione Aggiuntiva/ Additive Description	UDI-DI di base/ Basic UDI-DI
NMIM	Chiave Manipolo Mini	Implant Driver Mini Handpiece	++D748ISODEVICES7W
530HS001	Chiave Prensile HEX3.10	Retentive Wrench HEX3.10	++D748ISODEVICES7W
530HS017	Chiave Prensile Manipolo HEX3.10	Retentive Wrench HEX3.10	++D748ISODEVICES7W
530HS027	Driver Connector L23mm	Handpiece Driver Connector L23mm	++D748ISODEVICES7W
530HS028	Driver Connector L29mm	Handpiece Driver Connector L29mm	++D748ISODEVICES7W
530HS015	Driver Locator® L23mm	Handpiece Driver Locator® L23mm	++D748ISODEVICES7W
530HS016	Driver Locator® L29mm	Handpiece Driver Locator® L29mm	++D748ISODEVICES7W
530HR003	Implant Driver 3D Manipolo DR L31.2mm	Implant Driver 3D DR L31.2mm	++D748ISODEVICES7W
530HL010	Implant Driver 3D Manipolo DR L33.2mm	Implant Driver 3D DR L33.2mm	++D748ISODEVICES7W
530HR014	Implant Driver 3D Manipolo DR Large L37.8mm	Implant Driver 3D DR Large L37.8mm	++D748ISODEVICES7W
530HR013	Implant Driver 3D Manipolo DR Small L37.8mm	Implant Driver 3D DR Small L37.8mm	++D748ISODEVICES7W
530HR012	Implant Driver 3D Manipolo IR-IM-IW Large L37.9mm	Implant Driver 3D IR-IM-IW Large L37.9mm	++D748ISODEVICES7W
530HR011	Implant Driver 3D Manipolo IR-IM-IW Small L37.9mm	Implant Driver 3D IR-IM-IW Small L37.9mm	++D748ISODEVICES7W
530HR010	Implant Driver 3D Manipolo KN Small L35.9mm	Implant Driver 3D KN Small L35.9mm	++D748ISODEVICES7W
530HR002	Implant Driver 3D Manipolo KR Large L35.5mm	Implant Driver 3D KR Large L35.5mm	++D748ISODEVICES7W
530HR001	Implant Driver 3D Manipolo KR Small L35.5mm	Implant Driver 3D KR Small L35.5mm	++D748ISODEVICES7W
530HR009	Implant Driver 3D Manipolo KW Large L35.9mm	Implant Driver 3D KW Large L35.9mm	++D748ISODEVICES7W
530HR015	Implant Driver 3D Manipolo LR-LW L30.7mm	Implant Driver 3D LR-LW L30.7mm	++D748ISODEVICES7W
530HL011	Implant Driver 3D Manipolo LR-LW L30.7mm	Implant Driver 3D LR-LW L30.7mm	++D748ISODEVICES7W
530HS019	Implant Driver Manip TN TR TW L23mm	Implant driver TN TR TW L23mm	++D748ISODEVICES7W
530HS024	Implant Driver Manipolo AR L26mm	Implant Driver AR L26mm	++D748ISODEVICES7W
530HS025	Implant Driver Manipolo AW L26mm	Implant Driver AW L26mm	++D748ISODEVICES7W
530HS023	Implant Driver Manipolo DR L25mm	Implant Driver DR L25mm	++D748ISODEVICES7W
530HR008	Implant Driver Manipolo DR L26.8mm	Implant Driver DR L26.8mm	++D748ISODEVICES7W
530HL006	Implant Driver Manipolo DR L35mm	Implant Driver DR L35mm	++D748ISODEVICES7W
530HS006	Implant Driver Manipolo EN L26mm	Implant Driver EN L26mm	++D748ISODEVICES7W
530HS010	Implant Driver Manipolo EN L32mm	Implant Driver EN L32mm	++D748ISODEVICES7W
530HS007	Implant Driver Manipolo ER-EW L26mm	Implant Driver ER-EW L26mm	++D748ISODEVICES7W
530HS011	Implant Driver Manipolo ER-EW L32mm	Implant Driver ER-EW L32mm	++D748ISODEVICES7W
530HR007	Implant Driver Manipolo IR-IM-IW L26.5mm	Implant Driver IR L26.5mm	++D748ISODEVICES7W
530HS022	Implant Driver Manipolo IR-IW L25mm	Implant Driver IR-IW L25mm	++D748ISODEVICES7W
530HL005	Implant Driver Manipolo IR-IW L35mm	Implant Driver IR-IW L35mm	++D748ISODEVICES7W
530HR006	Implant Driver Manipolo KN L24.9mm	Implant Driver KN L24.9mm	++D748ISODEVICES7W
530HL003	Implant Driver Manipolo KN L33mm	Implant Driver KN L33mm	++D748ISODEVICES7W
530HS013	Implant Driver Manipolo KR L23mm	Implant Driver KR L23mm	++D748ISODEVICES7W
530HR004	Implant Driver Manipolo KR L25.45mm	Implant Driver KR L25.45mm	++D748ISODEVICES7W
530HL001	Implant Driver Manipolo KR L33mm	Implant Driver KR L33mm	++D748ISODEVICES7W
530HS029	Implant Driver Manipolo KS L24.8mm	Implant Driver KS L24.8mm	++D748ISODEVICES7W
530HL008	Implant Driver Manipolo KS L34.8mm	Implant Driver KS L34.8mm	++D748ISODEVICES7W
530HS030	Implant Driver Manipolo KT L24.8mm	Implant Driver KT L24.8mm	++D748ISODEVICES7W
530HL009	Implant Driver Manipolo KT L34.8mm	Implant Driver KT L34.8mm	++D748ISODEVICES7W
530HS014	Implant Driver Manipolo KW L23mm	Implant Driver KW L23mm	++D748ISODEVICES7W
530HR005	Implant Driver Manipolo KW L24.85mm	Implant Driver KW L24.85mm	++D748ISODEVICES7W
530HL002	Implant Driver Manipolo KW L33mm	Implant Driver KW L33mm	++D748ISODEVICES7W

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530HS026	Implant Driver Manipolo LR-LW L25mm	Implant Driver LR-LW L25mm	++D748ISODEVICES7W
530HL007	Implant Driver Manipolo LR-LW L35mm	Implant Driver LW L35mm	++D748ISODEVICES7W
530HS018	Implant Driver Manipolo SR L23mm	Implant driver SR L23mm	++D748ISODEVICES7W
520HS004	Prolunga Fresa HS L25mm	Drill Extension HS L25mm	++D748ISODEVICES7W
530HS021	Screwdriver Manipolo CR0.41 L29mm	Handpiece Driver CR0.41 L29mm	++D748ISODEVICES7W
530HL004	Screwdriver Manipolo CR0.41 L49mm	Handpiece Driver CR0.41 L49mm	++D748ISODEVICES7W
530HS002	Screwdriver Manipolo HEX0.90 L25mm	Handpiece Driver HEX0.90 L25mm	++D748ISODEVICES7W
530HS004	Screwdriver Manipolo HEX1.20 L25mm	Handpiece Driver HEX1.20 L25mm	++D748ISODEVICES7W
530HS005	Screwdriver Manipolo HEX1.20 L30mm	Handpiece Driver HEX1.20 L30mm	++D748ISODEVICES7W
530HS012	Screwdriver Manipolo HEX1.20 L30mm Ridotto	Handpiece Driver HEX1.20 L30mm Reduced	++D748ISODEVICES7W
530HS034	Screwdriver Manipolo HEX1.50 L25mm	Handpiece Driver HEX1.50 L25mm	++D748ISODEVICES7W
530HS035	Screwdriver Manipolo HEX1.50 L30mm	Handpiece Driver HEX1.50 L30mm	++D748ISODEVICES7W
530HS031	Screwdriver Manipolo UNIGRIP L25mm	Handpiece Driver UNIGRIP L25mm	++D748ISODEVICES7W
530HS032	Screwdriver Manipolo UNIGRIP L30mm	Handpiece Driver UNIGRIP L30mm	++D748ISODEVICES7W
530HS033	Screwdriver Manipolo UNIGRIP L30mm Ridotto	Handpiece Driver UNIGRIP L30mm Reduced	++D748ISODEVICES7W

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