

## 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:*

### BT SCREW/ *BT SCREW*, BT SCREW ETCHED / *BT SCREW ETCHED*, CHIODINO IN TITANIO/ *TITANIUM PIN*

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 IIB, in accordo alla regola 8 dell'allegato VIII del Regolamento UE 2017/745.  
*The medical devices have risk class IIB, according to rule 8 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 (DT10B), 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 (DT10B), 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:*

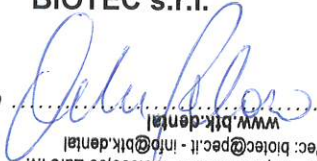
<b>Cod. Dispositivo/ Device Code</b>	<b>Descrizione Principale/ Main Description</b>	<b>Descrizione Aggiuntiva/ Additive Description</b>	<b>UDI-DI di base/ Basic UDI-DI</b>
167NA12C.05	BT Screw Ø1.2mm L4mm CR0.41 Kit 5pz	BT Screw Ø1.2mm L4mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA12G.05	BT Screw Ø1.2mm L6mm CR0.41 Kit 5pz	BT Screw Ø1.2mm L6mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA12J.05	BT Screw Ø1.2mm L8mm CR0.41 Kit 5pz	BT Screw Ø1.2mm L8mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA12L.05	BT Screw Ø1.2mm L10mm CR0.41 Kit 5pz	BT Screw Ø1.2mm L10mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA12N.05	BT Screw Ø1.2mm L12mm CR0.41 Kit 5pz	BT Screw Ø1.2mm L12mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA12Q.05	BT Screw Ø1.2mm L14mm CR0.41 Kit 5pz	BT Screw Ø1.2mm L14mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA15C.05	BT Screw Ø1.5mm L4mm CR0.41 Kit 5pz	BT Screw Ø1.5mm L4mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA15G.05	BT Screw Ø1.5mm L6mm CR0.41 Kit 5pz	BT Screw Ø1.5mm L6mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA15J.05	BT Screw Ø1.5mm L8mm CR0.41 Kit 5pz	BT Screw Ø1.5mm L8mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA15L.05	BT Screw Ø1.5mm L10mm CR0.41 Kit 5pz	BT Screw Ø1.5mm L10mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA15N.05	BT Screw Ø1.5mm L12mm CR0.41 Kit 5pz	BT Screw Ø1.5mm L12mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA15Q.05	BT Screw Ø1.5mm L14mm CR0.41 Kit 5pz	BT Screw Ø1.5mm L14mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA20C.05	BT Screw Ø2mm L4mm CR0.41 Kit 5pz	BT Screw Ø2mm L4mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA20G.05	BT Screw Ø2mm L6mm CR0.41 Kit 5pz	BT Screw Ø2mm L6mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA20J.05	BT Screw Ø2mm L8mm CR0.41 Kit 5pz	BT Screw Ø2mm L8mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA20L.05	BT Screw Ø2mm L10mm CR0.41 Kit 5pz	BT Screw Ø2mm L10mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA23C.05	BT Screw Ø2.3mm L4mm CR0.41 Kit 5pz	BT Screw Ø2.3mm L4mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA23G.05	BT Screw Ø2.3mm L6mm CR0.41 Kit 5pz	BT Screw Ø2.3mm L6mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA23J.05	BT Screw Ø2.3mm L8mm CR0.41 Kit 5pz	BT Screw Ø2.3mm L8mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
168NA12C.05	BT Screw Etched Ø1.2mm L4mm CR0.41 Kit 5pz	BT Screw Etched Ø1.2mm L4mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
168NA12G.05	BT Screw Etched Ø1.2mm L6mm CR0.41 Kit 5pz	BT Screw Etched Ø1.2mm L6mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
168NA12J.05	BT Screw Etched Ø1.2mm L8mm CR0.41 Kit 5pz	BT Screw Etched Ø1.2mm L8mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
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168NA15C.05	BT Screw Etched Ø1.5mm L4mm CR0.41 Kit 5pz	BT Screw Etched Ø1.5mm L4mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
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168NA20C.05	BT Screw Etched Ø2mm L4mm CR0.41 Kit 5pz	BT Screw Etched Ø2mm L4mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
168NA20G.05	BT Screw Etched Ø2mm L6mm CR0.41 Kit 5pz	BT Screw Etched Ø2mm L6mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
168NA20J.05	BT Screw Etched Ø2mm L8mm CR0.41 Kit 5pz	BT Screw Etched Ø2mm L8mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
168NA20L.05	BT Screw Etched Ø2mm L10mm CR0.41 Kit 5pz	BT Screw Etched Ø2mm L10mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
168NA23C.05	BT Screw Etched Ø2.3mm L4mm CR0.41 Kit 5pz	BT Screw Etched Ø2.3mm L4mm CR0.41 Kit 5pcs	++D748SCREWPINSWN

Cod. Dispositivo/ Device Code	Descrizione Principale/ Main Description	Descrizione Aggiuntiva/ Additive Description	UDI-DI di base/ Basic UDI-DI
168NA23G.05	BT Screw Etched Ø2.3mm L6mm CR0.41 Kit 5pz	BT Screw Etched Ø2.3mm L6mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
168NA23J.05	BT Screw Etched Ø2.3mm L8mm CR0.41 Kit 5pz	BT Screw Etched Ø2.3mm L8mm CR0.41 Kit 5pcs	++D748SCREWPINSWN
167NA65A.10	Chiodini in Titanio Ø0.65mm L2mm Kit 10pz	Titanium Pins Ø0.65mm L2mm Kit 10pcs	++D748SCREWPINSWN

Povolaro di Dueville, 2023-08-01

BIOTEC s.r.l.

 Andrea Peloso .....  
 CEO



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