

DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY

La Società **BIOTEC s.r.l.** Via Industria, 53 - 36031 Povolaro di Dueville (VI), fabbricante dei seguenti dispositivi medici:

*/The firm **Biotec s.r.l.** via Industria, 53 - 36031 Povolaro di Dueville (VI), manufacturer of the following medical devices:*

BT SCREW \ BT SCREW, BT SCREW ETCHED \ BT SCREW ETCHED, CHIODINO IN TITANIO \ TITANIUM PIN

dichiara sotto la propria responsabilità che i dispositivi medici, di cui all' oggetto, soddisfano i requisiti essenziali di sicurezza di cui all' allegato I della Direttiva 93/42/CEE e s.m.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 Directive 93/42/EEC and subsequent amendments.

Biotec inoltre dichiara, sotto la propria responsabilità quanto segue:

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

- questi dispositivi medici hanno classe di rischio IIB, in accordo alla regola 8 dell'allegato IX della Direttiva 93/42/CEE e s.m.i. (recepito in Italia con Decreto Legislativo 24 febbraio 1997 n° 46, modificato dal Decreto Legislativo 25 febbraio 1998 n° 95 e Decreto Legislativo del 25 gennaio 2010 n° 37).
/these medical devices have risk class IIB, according to Regulation 8 Annex IX of Directive 93/42/EEC and subsequent amendments (implemented in Italy with Legislative Decree N°. 46 February 24th, 1997, as amended by Legislative Decree 25th February 1998 and Legislative Decree N°. 95 of January 25th, 2010 N°. 37).
- i dispositivi medici sono progettati, fabbricati e posti in commercio secondo quanto riportato nel fascicolo tecnico di prodotto (FT10), 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 della Direttiva 93/42/CEE con numero 0426, in conformità a quanto prescritto dall' allegato II della suddetta direttiva. (Ultimo Certificato emesso: N. 024-05-02-DM emissione il 20-06-2019 – Ultimo certificato emesso in inglese: N. 024-05-02-DM emissione il 20-06-2019).
/the medical devices have been designed, manufactured and marketed as reported in Biotec technical dossier (FT10), following the full quality assurance system. This dossier has been declared conformity by ITALCERT, Notified Body under Directive 93/42/EEC with number 0426, in accordance with all requirements of Annex II of that Directive. (Last Certificate issued N°. 024-05-02-DM issue 20-06-2019 - Last certificate issued in English: N. 024-05-02-DM issue 20-06-2019).
- 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 medical devices is certified UNI EN ISO 9001 and UNI EN ISO 13485.

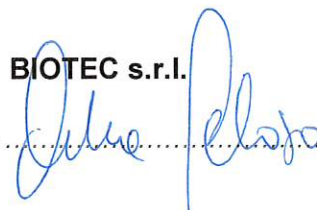
Di seguito si riporta l'elenco dei dispositivi inclusi nella presente Dichiarazione:

/Hereby we report a list of products included in the present Declaration:

Povolaro di Dueville, 20-06-2019

BIOTEC s.r.l.

Andrea Peloso
Ceo



Cod. Dispositivo/ Device Code	Descrizione Principale	Descrizione Aggiuntiva	Main Description	Additive Description
165NA20C.05	BT Screw	Ø2mm L4mm HEX1.20 Kit 5pz	BT Screw	Ø2mm L4mm HEX1.20 Kit 5pcs
165NA20G.05	BT Screw	Ø2mm L6mm HEX1.20 Kit 5pz	BT Screw	Ø2mm L6mm HEX1.20 Kit 5pcs
165NA20J.05	BT Screw	Ø2mm L8mm HEX1.20 Kit 5pz	BT Screw	Ø2mm L8mm HEX1.20 Kit 5pcs
165NA20L.05	BT Screw	Ø2mm L10mm HEX1.20 Kit 5pz	BT Screw	Ø2mm L10mm HEX1.20 Kit 5pcs
165NA23G.05	BT Screw	Ø2.3mm L6mm HEX1.20 Kit 5pz	BT Screw	Ø2.3mm L6mm HEX1.20 Kit 5pcs
165NA23J.05	BT Screw	Ø2.3mm L8mm HEX1.20 Kit 5pz	BT Screw	Ø2.3mm L8mm HEX1.20 Kit 5pcs
166NA20C.05	BT Screw Etched	Ø2mm L4mm HEX1.20 Kit 5pz	BT Screw Etched	Ø2mm L4mm HEX1.20 Kit 5pcs
166NA20G.05	BT Screw Etched	Ø2mm L6mm HEX1.20 Kit 5pz	BT Screw Etched	Ø2mm L6mm HEX1.20 Kit 5pcs
166NA20J.05	BT Screw Etched	Ø2mm L8mm HEX1.20 Kit 5pz	BT Screw Etched	Ø2mm L8mm HEX1.20 Kit 5pcs
166NA20L.05	BT Screw Etched	Ø2mm L10mm HEX1.20 Kit 5pz	BT Screw Etched	Ø2mm L10mm HEX1.20 Kit 5pcs
166NA23G.05	BT Screw Etched	Ø2.3mm L6mm HEX1.20 Kit 5pz	BT Screw Etched	Ø2.3mm L6mm HEX1.20 Kit 5pcs
166NA23J.05	BT Screw Etched	Ø2.3mm L8mm HEX1.20 Kit 5pz	BT Screw Etched	Ø2.3mm L8mm HEX1.20 Kit 5pcs
167NA15C.05	BT Screw	Ø1.5mm L4mm CR0.41 Kit 5pz	BT Screw	Ø1.5mm L4mm CR0.41 Kit 5pcs
167NA15G.05	BT Screw	Ø1.5mm L6mm CR0.41 Kit 5pz	BT Screw	Ø1.5mm L6mm CR0.41 Kit 5pcs
167NA15J.05	BT Screw	Ø1.5mm L8mm CR0.41 Kit 5pz	BT Screw	Ø1.5mm L8mm CR0.41 Kit 5pcs
167NA15L.05	BT Screw	Ø1.5mm L10mm CR0.41 Kit 5pz	BT Screw	Ø1.5mm L10mm CR0.41 Kit 5pcs
167NA15N.05	BT Screw	Ø1.5mm L12mm CR0.41 Kit 5pz	BT Screw	Ø1.5mm L12mm CR0.41 Kit 5pcs
167NA15Q.05	BT Screw	Ø1.5mm L14mm CR0.41 Kit 5pz	BT Screw	Ø1.5mm L14mm CR0.41 Kit 5pcs
167NA20C.05	BT Screw	Ø2mm L4mm CR0.41 Kit 5pz	BT Screw	Ø2mm L4mm CR0.41 Kit 5pcs
167NA20G.05	BT Screw	Ø2mm L6mm CR0.41 Kit 5pz	BT Screw	Ø2mm L6mm CR0.41 Kit 5pcs
167NA20J.05	BT Screw	Ø2mm L8mm CR0.41 Kit 5pz	BT Screw	Ø2mm L8mm CR0.41 Kit 5pcs
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167NA23C.05	BT Screw	Ø2.3mm L4mm CR0.41 Kit 5pz	BT Screw	Ø2.3mm L4mm CR0.41 Kit 5pcs
167NA23G.05	BT Screw	Ø2.3mm L6mm CR0.41 Kit 5pz	BT Screw	Ø2.3mm L6mm CR0.41 Kit 5pcs
167NA23J.05	BT Screw	Ø2.3mm L8mm CR0.41 Kit 5pz	BT Screw	Ø2.3mm L8mm CR0.41 Kit 5pcs
168NA15C.05	BT Screw Etched	Ø1.5mm L4mm CR0.41 Kit 5pz	BT Screw Etched	Ø1.5mm L4mm CR0.41 Kit 5pcs
168NA15G.05	BT Screw Etched	Ø1.5mm L6mm CR0.41 Kit 5pz	BT Screw Etched	Ø1.5mm L6mm CR0.41 Kit 5pcs
168NA15J.05	BT Screw Etched	Ø1.5mm L8mm CR0.41 Kit 5pz	BT Screw Etched	Ø1.5mm L8mm CR0.41 Kit 5pcs
168NA15L.05	BT Screw Etched	Ø1.5mm L10mm CR0.41 Kit 5pz	BT Screw Etched	Ø1.5mm L10mm CR0.41 Kit 5pcs
168NA15N.05	BT Screw Etched	Ø1.5mm L12mm CR0.41 Kit 5pz	BT Screw Etched	Ø1.5mm L12mm CR0.41 Kit 5pcs
168NA15Q.05	BT Screw Etched	Ø1.5mm L14mm CR0.41 Kit 5pz	BT Screw Etched	Ø1.5mm L14mm CR0.41 Kit 5pcs
168NA20C.05	BT Screw Etched	Ø2mm L4mm CR0.41 Kit 5pz	BT Screw Etched	Ø2mm L4mm CR0.41 Kit 5pcs
168NA20G.05	BT Screw Etched	Ø2mm L6mm CR0.41 Kit 5pz	BT Screw Etched	Ø2mm L6mm CR0.41 Kit 5pcs
168NA20J.05	BT Screw Etched	Ø2mm L8mm CR0.41 Kit 5pz	BT Screw Etched	Ø2mm L8mm CR0.41 Kit 5pcs
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168NA23C.05	BT Screw Etched	Ø2.3mm L4mm CR0.41 Kit 5pz	BT Screw Etched	Ø2.3mm L4mm CR0.41 Kit 5pcs
168NA23G.05	BT Screw Etched	Ø2.3mm L6mm CR0.41 Kit 5pz	BT Screw Etched	Ø2.3mm L6mm CR0.41 Kit 5pcs
168NA23J.05	BT Screw Etched	Ø2.3mm L8mm CR0.41 Kit 5pz	BT Screw Etched	Ø2.3mm L8mm CR0.41 Kit 5pcs
167NA65A	Chiodino in Titanio	Ø0.65mm L2mm	Titanium Pin	Ø0.65mm L2mm
167NA65A.10	Chiodini in Titanio	Ø0.65mm L2mm Kit 10pz	Titanium Pins	Ø0.65mm L2mm Kit 10pcs