

CERTIFICATE N° 024-05-02-DM
(in compliance with Annex II of the Directive 93/42/EEC)**ITALCERT**

certifies the

Full Quality Assurance System
applied for the design, manufacture and final inspection
of "Medical Devices" - MD -
by the manufacturer

BIOTEC S.r.l.

Via Industria, 53 – frazione POVOLARO
36031 DUEVILLE (VI) - ITALY

in the headquarters located in

Via Industria, 53 - frazione POVOLARO - 36031 DUEVILLE (VI) - ITALY
Via Industria, 57 - frazione POVOLARO - 36031 DUEVILLE (VI) - ITALY
Viale della Scienza 37 - frazione POVOLARO - 36031 DUEVILLE (VI) - ITALY

complies with the requirements stated in

Directive 93/42/EEC - Annex II (excluding point 4)

and authorizes the same manufacturer to mark

CE 0426

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



MANAGING DIRECTOR

1st Issue date
1998-12-18Current Emission
2019-06-20Expire date
2022-12-03

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DENTAL IMPLANTS, PROSTHETIC COMPONENTS and INSTRUMENTS (class IIb - IIa)

CODES	DESCRIPTION
103EXXXX	BT KLASSIC IMPLANT (E/E)
106IXXXX	BT KLASSIC IMPLANT (E/I)
107EXXXX	BT KONIC IMPLANT (E/E)
108IXXXX	BT KONIC IMPLANT (E/I)
111EXXXX	BT EVO IMPLANT DL (E/E)
112EXXXX	BT EVO IMPLANT (E/E)
115IXXXX	BT EVO IMPLANT DL (E/I)
116IXXXX	BT EVO IMPLANT (E/I)
120KXXXX	BT SAFE BONE DL (IMPLANT)
120SRXXX	BT SAFE TISSUE (IMPLANT)
122KXXXX	ISY KONE IMPLANT DL
123KWXXX	BT NANO IMPLANT DL
124EXXXX	ISY KONE IMPLANT (E/E)
125SRXXX	8NECK IMPLANT
126KXXXX	ISY KONE IMPLANT MACHINED DL
127EXXXX	BT KLASSIC IMPLANT (E/E) MACHINED
128KXXXX	BT SAFE BONE (IMPLANT)
129XXXXX	ISY KONE BL IMPLANT DL
129IXXXX	ISY KONE BL IMPLANT DL (E/I)
131EXXXX	ISY KONE BL IMPLANT (E/E)
150EXXXX	PTERIGO IMPLANT (E/E)
IMIXXXXXA	MINI IMPLANT
ITWXXXXXGCM	TWO IMPLANT
165NAXXX	BT SCREW HEX1.20
165NAXXX.XX	BT SCREW HEX1.20
166NAXXX	BT SCREW ECTHED HEX1.20
166NAXXX.XX	BT SCREW ECTHED HEX1.20
167NAXXX	BT SCREW CR0.41
167NAXXX.XX	BT SCREW CR0.41
168NAXXX	BT SCREW ECTHED CR0.41
168NAXXX.XX	BT SCREW ECTHED CR0.41
167NA65A	TITANIUM PIN
167NA65A.XX	TITANIUM PINS
201XXXXX	HEALING ABUTMENT
202XXXXX	HEALING ABUTMENT SP
203XXXXX	ANATOMICAL HEALING ABUTMENT
204XXXXX	MILLABLE HEALING ABUTMENT
205XXXXX	CASTABLE PLASTIC ABUTMENT
205XXXXX.XX	CASTABLE PLASTIC ABUTMENT
206XXXXX	CASTABLE PLASTIC ABUT. SP
207BUXXX	CASTABLE PLASTIC AB. BT4 SLIM
207NAXXX	CASTABLE PLASTIC ABUTMENT BT4
210XXXXX	TEMPORARY ABUTMENT
214XXXXX	TRANSFER ABUTMENT
215XXXXX	TEMPORARY ABUTMENT PEEK
219XXXXX	AESTHETIC ABUTMENT
220XXXXX	ABUTMENT (STRAIGHT OR ANGLED OR SOLID OR OCTA)
223IXXXX	FRICTION ABUTMENT
224XXXXX	ABUTMENT (STRAIGHT OR ANGLED)
230XXXXX	MILLABLE ABUTMENT
231XXXXX	BWB ABUTMENT BT
231XXXXX.XX	BWB ABUTMENT BT

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CODES	DESCRIPTION
232XXXXX	BWB RING
232XXXXX.XX	BWB RING
233XXXXX	BWB EXTENSION – BWB FEMALE JOINT – BWB MALE JOINT - BWB MALE JOINT SHORT - BWB FEMALE JOINT SHORT
233XXXXX.XX	BWB EXTENSION – BWB FEMALE JOINT – BWB MALE JOINT - BWB MALE JOINT SHORT - BWB FEMALE JOINT SHORT
234XXXXX	WINGS EXTENSION
234XXXXX.XX	WINGS ABUTMENT- WINGS EXTENSION
236XXXXX	TITANIUM BASE
237XXXXX	TITANIUM BASE + CAP
239XXXXX	MILLABLE ABUTMENT
240XXXXX	CoCr ABUTMENT
245XXXXX	GOLD ABUTMENT
246XXXXX	BT LINK
247XXXXX	BASE BT LINK NO CAP
247XXXXX.XX	BASE BT LINK NO CAP
260XXXXX	LOCATOR® ABUTMENT
265XXXXX	BT4 ABUTMENT
266XXXXX	BT4 ANGLED ABUTMENT
267XXXXX	BT4 ABUTMENT
268XXXXX	BT4 SLIM ABUTMENT
269XXXXX	BT4 SLIM ABUTMENT
330XXXXX.XX	COVERING CAPS BT4
340XXXXX	DIRECTIONAL TRANSFER-ABUTM. (STRAIGHT OR CONIC OR MILLABLE)
40XHXXXX	DRILL
41XHXXXX	DRILL
42XHXXXX	DRILL
430HXXXX	COUNTERSINK
431HXXXX	COUNTERSINK
432HXXXX	COUNTERSINK
433HXXXX	COUNTERSINK
433HXXXX.R	COUNTERSINK REDUCED
434HXXXX	COUNTERSINK
435HXXXX	BONE PROFILER
436HXXXX	COUNTERSINK 3D
437HXXXX	PIT COUNTERSINK
461HXXXX	SCREW TAP
462HXXXX	SCREW TAP
463HXXXX	SCREW TAP
464HXXXX	SCREW TAP
466HXXXX	SCREW TAP
467HXXXX	SCREW TAP
468HXXXX	PIT DRILL
47XHXXXX	SCREW TAP 3D
490HXXXX	TISSUE PUNCH
491HXXXX	TISSUE PUNCH 3D
492HXXXX	TREPHINE DRILL
520HXXXX	DRILL EXTENSION
530HXXXX	DRIVER OR SCREWDRIVER OR WRENCH
660XXXXX	PROSTHETIC KIT BWB
690NAXXX.X4	REPLACEMENT MALES LOCATOR®
690NAXXX	RETENTION SCREW OR SCREW
690NAXXX.XX	RETENTION SCREW OR SCREW
CCXXXXXX	CASTABLE PLASTIC ABUTMENT
CCXXXXXX-XX	CASTABLE PLASTIC ABUTMENT
COXXXXXX	GOLD ABUTMENT
FFXXXXXX	DRILL
FMIXX	DRILL MINI

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CODES	DESCRIPTION
FMIXXX	DRILL MINI
FPXXXXXX	DRILL
GGXXXXXX	HEALING ABUTMENT
HHXXXXXX	SCREW TAP
MEOXXXXX	AESTHETIC ABUTMENT TWO
MEXXXXXX	AESTHETIC ABUTMENT
MLXXX	LOCATOR® ABUTMENT
MMCXXXXX	CEMENTABLE ABUTMENT TWO
MMI17XX	ABUTMENT MINI
MMXXXXXX	ABUTMENT
MUXXX	TISSUE PUNCH
415HS350	TISSUE PUNCH 3D HS Ø3.5mm L28mm
415HS500	BONE PROFILER HS Ø5mm L30mm
433HS280	PILOT DRILL HS Ø2.8mm L29mm
690NA011	REPLACEMENT MALES LOCATOR®
690NA022	KIT LOCATOR® METAL CAP + BLOCKOUT SPACER
COR1770	RETENTIVE HOUSING MINI IMPLANT
NMIM	IMPLANT DRIVER MINI HANDPIECE
VLE14TIT	LINGUAL SCREW AESTHETIC ABUTMENT M1.4

Milan, 2019-06-20

dr. ing. Roberto CUSOLITO



Managing Director