



ITALCERT

CERTIFICATO 292-01-00-DM

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ITALCERT S.r.l.

certifica che il
certifies that the

Sistema Completo di Garanzia della Qualità messo in atto
per la progettazione, la fabbricazione ed il controllo finale di Dispositivi Medici
*Full Quality Assurance System applied
for the design, manufacture and final inspection of Medical Devices*

dal Fabbricante
by the Manufacturer

OVERMED S.r.l.

Piazza Velasca, 8 – 20122 MILANO (MI) - ITALIA

nella sede operativa di
in the operational headquarter located in

Via Lucania, 23/25 - 20090 BUCCINASCO (MI) - ITALIA

è conforme ai requisiti previsti dalla
complies with the requirements stated in

Direttiva 93/42/CEE - Allegato II (con esclusione del punto 4)
Directive 93/42/EEC - Annex II (excluding point 4)

ed autorizza lo stesso fabbricante ad apporre la marcatura
and authorizes the manufacturer to mark

CE 0426

in accordo ai criteri previsti dall'Al. XII della Direttiva 93/42/CEE
sui dispositivi medici riportati nell'Allegato 1 del presente Certificato
*in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
on the medical devices reported in Annex 1 of this Certificate*

Dr. Ing. Roberto Cusolito
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Data di rilascio
First Issue Date
2015-05-11

Data di rinnovo
Renewal Date
2020-04-21

Data di scadenza
Expire Date
2024-05-26

Il presente Certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato I
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ITALCERT S.r.l. | Organismo Notificato n° 0426 | Viale Sarca, 336 – 20126 Milano (MI)
tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

Allegato 1 al Certificato 292-01-00-DM
Annex 1 to Certificate 292-01-00-DM

Pagina 1 di 3
Page 1 of 3

**DISPOSITIVI MEDICI IMPIANTABILI PER ORTOPEDIA
E RELATIVI ACCESSORI E STRUMENTARIO**
(classe IIb e IIa)
IMPLANTABLE MEDICAL DEVICES intended for ORTHOPAEDICS
ACCESSORIES and INSTRUMENTS (class IIb - IIa)

VITI MINIARS - VITI FOX-	MINIARS-FOX SCREWS
Viti cannulate torx 6 (codice A050xxxx)	Cannulated screws torx 6 (code A050xxxx)
Viti cannulate torx 7 (codice A070xxxx)	Cannulated screws torx 7 (code A070xxxx)
Viti cannulate per la mano (codice AHxxxxxx)	Cannulated screws for hand (code AHxxxxxx)

VITI Tool	Tool SCREWS
Viti cannulate (codice ATLxxxxx)	Cannulated screws (code ATLxxxxx)

VITI Artrobone	Artrobone SCREWS
Viti cannulate (codice AABxxxxx - AABxxxxxx)	Cannulated screws (code AABxxxxx - AABxxxxxx)

STRUMENTI CHIRURGICI PER VITI A DUE FILETTI	HEADLESS COMPRESSION SCREWS SURGICAL INSTRUMENTS
Frese cannulate svasate (codice K100xxxx)	Countersink cannulated drills (code K100xxxx)
Frese cannulate lunghe (codice K200xxxxx)	Cannulated drills long (code K200xxxxx)

VITE PER PIEDE PIATTO e STRUMENTI CHIRURGICI	SCREWS FOR FLAT FOOT AND SURGICAL INSTRUMENTS
Viti subtalari in Ti gr 5 (codice SSxxxx - SSxxxxS)	Subtalar screws in Ti gr 5 (code SSxxxx - SSxxxxS)
Viti subtalari in Ti gr 7 (codice SSEKxxxx - SSEKxxxxS)	Subtalar screws in Ti gr 7 (code SSEKxxxx - SSEKxxxxS)
Viti APSS2 (codice APSS2xx)	APSS2 screws (code APSS2xx)
Fresa Ø3 piena (codice KAPSS3015)	Drill Ø3 (code KAPSS3015)

VITI ORTOPEDICHE	ORTHOPEDIC SCREWS
Viti a due filetti - Viti ARS (codice HS30xx - A10030xx)	Headless compression screw - Viti ARS (code HS30xx - A10030xx)
Viti a due filetti - Viti SLANT (codice HS130xx - A12030xx)	Headless compression screw - Viti SLANT (code HS130xx - A12030xx)
Viti MINI SLANT (codice A08025xx)	MINI SLANT screw (code A08025xx)
Viti a rottura programmata SWING-OFF (codice SOxxxxS - A150xxxx)	SWING-OFF self-breaking screw (code SOxxxxS - A150xxxx)
Viti BRISS (codice BRISSxx)	BRISS screws (code BRISSxx)
Viti BRISS cannulate (codice BRISSxxC)	BRISS cannulated screws (code BRISSxxC)
Viti per il trattamento chirurgico del piede diabetico (codice DFSxx - DFSxxS)	Screws for diabetic foot treatment (code DFSxx - DFSxxS)

STRUMENTI CHIRURGICI PER ORTOPEDIA	ORTHOPEDIC SURGICAL INSTRUMENTS
Fili guida (codice 4.xxx.xxx)	Guide wire (code 4.xxx.xxx)
Fresa cannulata (codice 4.xxx.002)	Cannulated drill (code 4.xxx.002)
Fresa per Ars e Slant (codice K10100xx)	Drill for Ars and Slant (code K10100xx)
Cacciavite per Minislant (codice K1010040)	Minislant Screwdriver (code K1010040)
Cacciavite per Ars e Slant (codice K1010030)	Ars and Slant Screwdriver (code K1010030)

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Allegato 1 al Certificato 292-01-00-DM

Annex 1 to Certificate 292-01-00-DM

Pagina 2 di 3
Page 2 of 3

STRUMENTI CHIRURGICI MONOUSO	SINGLE-USE SURGICAL INSTRUMENTS
Fili guida (codice GW.080.xx - GW.100.xx)	Guide wire (code GW.080.xx - GW.100.xx)
Manici (codice HANDLE - HANDLE.80.C - HANDLE.100.C)	Handle (code HANDLE - HANDLE.80.C - HANDLE.100.C)
Terminali MiniArs/Fox e Tool (codice KC.FOXTL.T7 K.FOXTL.T7 DC.FOXTL.xx)	MiniArs/Fox and Tool Ends (code KC.FOXTL.T7 K.FOXTL.T7 DC.FOXTL.xx)
Terminali Ars/Slant (codice KC.AS.HEX2- DC.AS.20xx)	Ars/Slant Ends (code KC.AS.HEX2- DC.AS.20xx)
Terminali MiniSlant (codice KC.MSL.HEX15)	MiniSlant Ends (code KC.MSL.HEX15)
Terminali Swing-off (codice KC.SWG.TRI)	Swing-off Ends (code KC.SWG.TRI)
Terminali Subtalar (codice EXT.SS - KC.SS.HEX35 - BT.SS.xx -DIL.SS - PUSH.GW)	Subtalar Ends (code EXT.SS - KC.SS.HEX35 - BT.SS.xx -DIL.SS - PUSH.GW)
Terminali Sistema APSS2 (codice TRC.APSS- K.APSS.HEX32 - D.APSS.30)	APSS2 Ends (code TRC.APSS- K.APSS.HEX32 - D.APSS.30)

VITE MAAG	MAAG SCREWS
Viti cannulate Ø 8.0 (VITE MAAG) filetto 16mm Ti gr. 5 (codice 3.801.xxx - 3.801.xxx.S)	Cannulated screws Ø 8.0 (MAAG screw) thread 16mm Ti gr. 5 (code 3.801.xxx - 3.801.xxx.S)
Viti cannulate Ø 8.0 (VITE MAAG) filetto 32mm Ti gr. 5 (codice 3.802.xxx - 3.802.xxx.S)	Cannulated screws Ø 8.0 (MAAG screw) thread 32mm Ti gr. 5 (code 3.802.xxx - 3.802.xxx.S)
Accessori - Sistema di iniezione (codice 4.28C.xxx - 4.28C.xxx.S)	Accessories - Injection system (code 4.28C.xxx - 4.28C.xxx.S)

VITI CANNULATE	CANNULATED SCREWS
Viti cannulate Ø 2.0 filetto corto Ti gr. 5 (codice 3.202.xxx - 3.202.xxx.S)	Cannulated screws Ø 2.0 short thread Ti gr. 5 (code 3.202.xxx - 3.202.xxx.S)
Viti cannulate Ø 2.4 filetto corto Ti gr. 5 (codice 3.242.xxx - 3.242.xxx.S)	Cannulated screws Ø 2.4 short thread Ti gr. 5 (code 3.242.xxx - 3.242.xxx.S)
Viti cannulate testa conica Ø 2.7 filetto corto Ti gr. 5 (codice 3.273.xxx - 3.273.xxx.S)	Cannulated screws conical head Ø 2.7 short thread Ti gr. 5 (code 3.273.xxx - 3.273.xxx.S)
Viti cannulate Ø 2.7 filetto completo Ti gr. 5 (codice 3.271.xxx - 3.271.xxx.S)	Cannulated screws Ø 2.7 full thread Ti gr. 5 (code 3.271.xxx - 3.271.xxx.S)
Viti cannulate Ø 2.7 filetto corto Ti gr. 5 (codice 3.272.xxx - 3.272.xxx.S)	Cannulated screws Ø 2.7 short thread Ti gr. 5 (code 3.272.xxx - 3.272.xxx.S)
Viti cannulate Ø 3.0 filetto completo Lega Ti-Nb (codice 1.301.xxx - 1.301.xxx.S)	Cannulated screws Ø 3.0 full thread Ti-Nb alloy (code 1.301.xxx - 1.301.xxx.S)
Viti cannulate Ø 3.0 filetto corto Lega Ti-Nb (codice 1.302.xxx - 1.302.xxx.S)	Cannulated screws Ø 3.0 short thread Ti-Nb alloy (code 1.302.xxx - 1.302.xxx.S)
Viti cannulate Ø 3.5 filetto completo Lega Ti-Nb (codice 1.351.xxx - 1.351.xxx.S)	Cannulated screws Ø 3.5 full thread Ti-Nb alloy (code 1.351.xxx - 1.351.xxx.S)
Viti cannulate Ø 3.5 filetto corto Lega Ti-Nb (codice 1.352.xxx - 1.352.xxx.S)	Cannulated screws Ø 3.5 short thread Ti-Nb alloy (code 1.352.xxx - 1.352.xxx.S)
Viti cannulate Ø 3.5 filetto completo Ti gr. 5 (codice 3.351.xxx - 3.351.xxx.S)	Cannulated screws Ø 3.5 full thread Ti gr. 5 (code 3.351.xxx - 3.351.xxx.S)
Viti cannulate Ø 3.5 filetto corto Ti gr. 5 (codice 3.352.xxx - 3.352.xxx.S)	Cannulated screws Ø 3.5 short thread Ti gr. 5 (code 3.352.xxx - 3.352.xxx.S)
Viti cannulate Ø 4.0 filetto lungo Lega Ti-Nb (codice 1.401.xxx - 1.401.xxx.S)	Cannulated screws Ø 4.0 thread lungo Ti-Nb alloy (code 1.401.xxx - 1.401.xxx.S)
Viti cannulate Ø 4.0 filetto corto Lega Ti-Nb (codice 1.402.xxx - 1.402.xxx.S)	Cannulated screws Ø 4.0 short thread Lega Ti-Nb (code 1.402.xxx - 1.402.xxx.S)
Viti cannulate Ø 4.0 filetto completo Ti gr. 5 (codice 3.401.xxx - 3.401.xxx.S)	Cannulated screws Ø 4.0 full thread Ti gr. 5 (code 3.401.xxx - 3.401.xxx.S)
Viti cannulate Ø 4.0 filetto corto Ti gr. 5 (codice 3.402.xxx - 3.402.xxx.S)	Cannulated screws Ø 4.0 short thread Ti gr. 5 (code 3.402.xxx - 3.402.xxx.S)
Viti cannulate Ø 4.5 filetto completo Lega Ti-Nb (codice 1.451.xxx - 1.451.xxx.S)	Cannulated screws Ø 4.5 full thread Ti-Nb alloy (code 1.451.xxx - 1.451.xxx.S)
Viti cannulate Ø 4.5 filetto corto Lega Ti-Nb (codice 1.452.xxx - 1.452.xxx.S)	Cannulated screws Ø 4.5 short thread Ti-Nb alloy (code 1.452.xxx - 1.452.xxx.S)

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Allegato 1 al Certificato 292-01-00-DM Annex 1 to Certificate 292-01-00-DM

Pagina 3 di 3
Page 3 of 3

VITI CANNULATE	CANNULATED SCREWS
Viti cannulate Ø 4.5 filetto completo Ti gr. 5 (codice 3.451.xxx - 3.451.xxx.S)	Cannulated screws Ø 4.5 full thread Ti gr. 5 (code 3.451.xxx - 3.451.xxx.S)
Viti cannulate Ø 4.5 filetto corto Ti gr. 5 (codice 3.452.xxx - 3.452.xxx.S)	Cannulated screws Ø 4.5 short thread Ti gr. 5 (code 3.452.xxx - 3.452.xxx.S)
Viti cannulate Ø 5.0 filetto corto Ti gr. 5 (codice 3.501.xxx - 3.501.xxx.S)	Cannulated screws Ø 5.0 short thread Ti gr. 5 (code 3.501.xxx - 3.501.xxx.S)
Viti cannulate Ø 6.5 filetto 16mm Lega Ti-Nb (codice 1.651.xxx - 1.651.xxx.S)	Cannulated screws Ø 6.5 thread 16mm Ti-Nb alloy (code 1.651.xxx - 1.651.xxx.S)
Viti cannulate Ø 6.5 filetto 32mm Lega Ti-Nb (codice 1.652.xxx - 1.652.xxx.S)	Cannulated screws Ø 6.5 thread 32mm Ti-Nb alloy (code 1.652.xxx - 1.652.xxx.S)
Viti cannulate Ø 6.5 filetto completo Lega Ti-Nb (codice 1.653.xxx - 1.653.xxx.S)	Cannulated screws Ø 6.5 full thread Ti-Nb alloy (code 1.653.xxx - 1.653.xxx.S)
Viti cannulate Ø 7.0 filetto 16mm AISI 316L (codice 4.701.xxx - 4.701.xxx.S)	Cannulated screws Ø 7.0 thread 16mm AISI 316L (code 4.701.xxx - 4.701.xxx.S)
Viti cannulate Ø 7.0 filetto 32mm AISI 316L (codice 4.702.xxx - 4.702.xxx.S)	Cannulated screws Ø 7.0 thread 32mm AISI 316L (code 4.702.xxx - 4.702.xxx.S)
Viti cannulate Ø 7.0 filetto completo AISI 316L (codice 4.703.xxx - 4.703.xxx.S)	Cannulated screws Ø 7.0 full thread AISI 316L (code 4.703.xxx - 4.703.xxx.S)
Viti cannulate Ø 7.2 filetto 16mm Ti gr. 5 (codice 3.721.xxx - 3.721.xxx.S)	Cannulated screws Ø 7.2 thread 16mm Ti gr. 5 (code 3.721.xxx - 3.721.xxx.S)
Viti cannulate Ø 7.3 filetto 16mm Lega Ti-Nb (codice 1.731.xxx - 1.731.xxx.S)	Cannulated screws Ø 7.3 thread 16mm Ti-Nb alloy (code 1.731.xxx - 1.731.xxx.S)
Viti cannulate Ø 7.3 filetto 32mm Lega Ti-Nb (codice 1.732.xxx - 1.732.xxx.S)	Cannulated screws Ø 7.3 thread 32mm Ti-Nb alloy (code 1.732.xxx - 1.732.xxx.S)
Viti cannulate Ø 7.3 filetto completo Lega Ti-Nb (codice 1.733.xxx - 1.733.xxx.S)	Cannulated screws Ø 7.3 full thread Ti-Nb alloy (code 1.733.xxx - 1.733.xxx.S)
Viti cannulate testa piatta Ø 3.5 filetto corto Ti gr. 5 (codice 3.353.xxx - 3.353.xxx.S)	Cannulated screws flat head Ø 3.5 short thread Ti gr. 5 (code 3.353.xxx - 3.353.xxx.S)
Viti cannulate testa piatta Ø 4.0 filetto corto Ti gr. 5 (codice 3.403.xxx - 3.403.xxx.S)	Cannulated screws flat head Ø 4.0 short thread Ti gr. 5 (code 3.403.xxx - 3.403.xxx.S)
Viti cannulate testa piatta Ø 4.5 filetto corto Ti gr. 5 (codice 3.453.xxx - 3.453.xxx.S)	Cannulated screws flat head Ø 4.5 short thread Ti gr. 5 (code 3.453.xxx - 3.453.xxx.S)
Viti cannulate testa piatta Ø 5.5 filetto corto Ti gr. 5 (codice 3.551.xxx - 3.551.xxx.S)	Cannulated screws flat head Ø 5.5 short thread Ti gr. 5 (code 3.551.xxx - 3.551.xxx.S)
Viti cannulate testa piatta Ø 6.0 filetto corto Ti gr. 5 (codice 3.601.xxx - 3.601.xxx.S)	Cannulated screws flat head Ø 6.0 short thread Ti gr. 5 (code 3.601.xxx - 3.601.xxx.S)
Accessori - Rondelle (codice x.xxx.000)	Accessories - Washer (code x.xxx.000)

Milano, 2020-04-21


Dr. Ing. Roberto Cusolito
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

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