CERTIFICATO CE

Certificato n. 1363/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

NORICUM, S.L.

28703 SAN SEBASTIÁN DE LOS REYES (MADRID) - AVDA. FUENTE NUEVA 14 - NAVE 3A (ESP) - Spain

mantiene nello stabilimento di:

28703 SAN SEBASTIÁN DE LOS REYES (MADRID) - AVDA. FUENTE NUEVA 14 - NAVE 3A (ESP) - Spain

25123 TORREFARRERA (LÉRIDA) - C/PINYANA 7, P.I. LES COMES (ESP) - Spain

un sistema qualità che assicura la conformità dei seguenti prodotti:

Componente protesico dentale

Vite di fissaggio protesico

Cilindro transepiteriale

Vite di guarigione

Vite

Vite tappo

Vite tappo miniconica

Impianti dentali

Micro impianti

Frese dentali

Perno di fissaggio

Mini vite di fissaggio

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Emesso il:	2010-07-12
Data aggiornamento:	2020-12-17
Sostituisce:	2020-11-24
Data scadenza:	2024-05-26

Giorgi Fulvio
IMQ

DocuSign

CERTIFICATO CE

Certificato n. 1363/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Riferimento pratiche IMQ:

10AJ00246; 10AL00142; DM15A0415190-01; DM15A0415190-01; DM15A0550869-01; DM17-0015612-01; DM17-0015011-01; DM17-0014997-01; DM18-0026436-01; DM19-0047175-01; DM20-0048209-01; DM20-0056382-01; DM20-0055312-01; DM20-0058386-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2010-07-12
Data aggiornamento:	2020-12-17
Sostituisce:	2020-11-24
Data scadenza:	2024-05-26

Giorgi Fulvio

IMQ

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CERTIFICATO CE

Certificato n. 1363/MDD

Allegato

Componente protesico dentale

Vite di fissaggio protesico

Cilindro transepiteriale

Vite di guarigione

Vite

Vite tappo

Vite tappo miniconica

Impianti dentali

Micro impianti

Frese dentali

Perno di fissaggio

Mini vite di fissaggio

Modd. come da documento "Allegato al Certificato CE no. 1363/MDD - Elenco dei Dispositivi" rev. 1 del 2020/12/17; tale allegato costituisce parte integrante e sostanziale del presente certificato.

Emesso il:	2010-07-12
Data aggiornamento:	2020-12-17
Sostituisce:	2020-11-24
Data scadenza:	2024-05-26

Giorgi Fulvio
IMQ
DocuSign

EC CERTIFICATE

Certificate No 1363/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

NORICUM, S.L.

28703 SAN SEBASTIÁN DE LOS REYES (MADRID) - AVDA. FUENTE NUEVA 14 - NAVE 3A (ESP) - Spain

manages in the factory of:

28703 SAN SEBASTIÁN DE LOS REYES (MADRID) - AVDA. FUENTE NUEVA 14 - NAVE 3A (ESP) - Spain

25123 TORREFARRERA (LÉRIDA) - C/PINYANA 7, P.I. LES COMES (ESP) - Spain

a quality assurance system ensuring the conformity of the following products:

Miniconic abutment

Prosthesis fixation screw

Orthodontic cylinder

Healing abutment

Abutment

Abutment cap

Miniconic abutment cap

Dental implants

Micro implant

Dental drills

Fixing pin

Mini fixing screw

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Date:	2010-07-12
Updated:	2020-12-17
Substitution Date:	2020-11-24
Expiry Date:	2024-05-26

Giorgi Fulvio

IMQ

DocuSign

EC CERTIFICATE

Certificate No 1363/MDD

Full Quality Assurance System Approval Certificate

Reference to IMQ files Nos:

10AJ00246; 10AL00142; DM15A0415190-01; DM15A0415190-01; DM15A0550869-01; DM17-0015612-01; DM17-0015011-01; DM17-0014997-01; DM18-0026436-01; DM19-0047175-01; DM20-0048209-01; DM20-0056382-01; DM20-0055312-01; DM20-0058386-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2010-07-12
Updated:	2020-12-17
Substitution Date:	2020-11-24
Expiry Date:	2024-05-26

Giorgi Fulvio
IMQ

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This Approval Certificate is subjected to the provisions laid down in the "IMQ regulation for the certification of Medical Devices - CE Marking - Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 1363/MDD

Annex

Miniconic abutment

Prosthesis fixation screw

Orthodontic cylinder

Healing abutment

Abutment

Abutment cap

Miniconic abutment cap

Dental implants

Micro implant

Dental drills

Fixing pin

Mini fixing screw

Type ref. as to document "Annex of EC Certificate no.1363/MDD - Device List" rev. 1 dated 2020/12/17; this annex is integral and substantial part of this certificate.

Date:	2010-07-12
Updated:	2020-12-17
Substitution Date:	2020-11-24
Expiry Date:	2024-05-26

Giorgi Fulvio
IMQ

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Allegato al Certificato CE n. 1363/MDD- Elenco dei Dispositivi

Annex of EC Certificate no. 1363/MDD - Device List

rev. 1 del/of **2020/12/17**

Categoria di dispositivo: Device category:	**Componente protesico dentale** Miniconic abutment
Modello/i: Model(s):	**MCR100; MCR200; MCR300; MCR400; MCR500; MCA100; MCA200; MCA300; MCA400; MCA500; MCIR100; MCIR200; MCIR300; MCIR400; MCIR500; MCIA100; MCIA200; MCIA300; MCIA400; MCIA500; MCICE150; MCICE200; MCICE300; MCICE400; MCICE500; MCICE600; MCICE700; MCICR150; MCICR200; MCICR300; MCICR400; MCICR500; MCICR600; MCICR700.**
Marca/Marche: Trade mark(s):	./.

Categoria di dispositivo: Device category:	**Vite di fissaggio protesico** Prosthesis fixation screw
Modello/i: Model(s):	**TPR; TPA; TPIPR; TPIPA; TPIPIE; TPIPIR.**
Marca/Marche: Trade mark(s):	./.

Categoria di dispositivo: Device category:	**Cilindro transepiteriale** Orthodontic cylinder
Modello/i: Model(s):	**CIL1MCR; CIL2MCR; CIL1MCA; CIL2MCA; CILRIPR; CILRIPA; CILFIPR; CILFIPA; CILRIPIE; CILRIPIR;CILFIPIE; CILFIPIR; CILUNHIE; CILUNHIR; CILUNHER; CILUNHEA; CILUNR; CILUNA; CILSMIE; CILSMIR.**
Marca/Marche: Trade mark(s):	./.

Categoria di dispositivo: Device category:	**Vite di guarigione** Healing abutment
Modello/i: Model(s):	**PCR100; PCR200; PCR300; PCR400; PCR550; PCR600; PCR700; PCA100; PCA200; PCA300; PCA400; PCA550; PCA600; PCA700; PCIR100; PCIR200; PCIR300; PCIR400; PCIR500; PCIA100; PCIA200; PCIA300; PCIA400; PCIA500; PCA500; PCR500; PCICE36040; PCICE36300; PCICE36500; PCICE36700; PCICE50300; PCICE50500; PCICE50700; PCICR40040; PCICR40300; PCICR40500; PCICR40700; PCICR50040; PCICR50300; PCICR50500; PCICR50700; PCICE36I00; PCICE36200; PCICR40100; PCICR40200.**
Marca/Marche: Trade mark(s):	./.

Allegato al Certificato CE n. 1363/MDD- Elenco dei Dispositivi

Annex of EC Certificate no. 1363/MDD - Device List

rev. 1 del/of **2020/12/17**

Categoria di dispositivo: Device category:	**Vite** Abutment
Modello/i: Model(s):	**UNR100; UNR200; UNR300; UNR400; UNR500; UNA100; UNA200; UNA300; UNA400; UNA500; UNCRR100; UNCFR100; UNCRA100; UNCFA100; UNCRIE100; UNCFIE100; UNCRIR100; UNCFIR100; UNICE700; UNICE900; UNICR700; UNICR900.**
Marca/Marche: Trade mark(s):	./.

Categoria di dispositivo: Device category:	**Vite tappo** Abutment cap
Modello/i: Model(s):	**TAPUNR; TAPUNA**
Marca/Marche: Trade mark(s):	./.

Categoria di dispositivo: Device category:	**Vite tappo miniconica** Miniconic abutment cap
Modello/i: Model(s):	**TAPMCR; TAPMCA**
Marca/Marche: Trade mark(s):	./.

Allegato al Certificato CE n. 1363/MDD- Elenco dei Dispositivi

Annex of EC Certificate no. 1363/MDD - Device List

rev. 1 del/of **2020/12/17**

Categoria di dispositivo: Device category:	**Impianti dentali** Dental implants
Modello/i: Model(s):	**IP0ER400070; IP0ER400085; IP0ER400100; IP0ER400115; IP0ER400130; IP0ER400150; IP0ER400180; IP0EA500070; IP0EA500085; IP0EA500100; IP0EA500115; IP0EA500130; IP0EA500150; IP0EA500180; IP0IE350070; IP0IE350085; IP0IE350100; IP0IE350115; IP0IE350130; IP0IE350150; IP0IE350180; IP0IR400070; IP0IR400085; IP0IR400100; IP0IR400115; IP0IR400130; IP0IR400150; IP0IR400180; IP0IR500070; IP0IR500085; IP0IR500100; IP0IR500115; IP0IR500130; IP0IR500150; IP0IR500180; IP3ER400070; IP3ER400085; IP3ER400100; IP3ER400115; IP3ER400130; IP3ER400150; IP3ER400180; IP3EA500070; IP3EA500085; IP3EA500100; IP3EA500115; IP3EA500130; IP3EA500150; IP3EA500180; IP3IE350070; IP3IE350085; IP3IE350100; IP3IE350115; IP3IE350130; IP3IE350150; IP3IE350180; IP3IR400070; IP3IR400085; IP3IR400100; IP3IR400115; IP3IR400130; IP3IR400150; IP3IR400180; IP3IR500070; IP3IR500085; IP3IR500100; IP3IR500115; IP3IR500130; IP3IR500150; IP3IR500180; IP0IE500085; IP0IE500100; IP0IE500115; IP0IE500130; IP0IE500150; IP0IE430085; IP0IE430100; IP0IE430115; IP0IE430130; IP0IE430150; IP0ER400070-2; IP0ER400085-2; IP0ER400100-2; IP0ER400115-2; IP0ER400130-2; IP0ER400150-2; IP0ER400180-2; IP0ER400070-3; IP0ER400085-3; IP0ER400100-3; IP0ER400115-3; IP0ER400130-3; IP0ER400150-3; IP0ER400180-3; IP0IR400070-2; IP0IR400085-2; IP0IR400100-2; IP0IR400115-2; IP0IR400130-2; IP0IR400150-2; IP0IR400180-2; IP0IR400070-3; IP0IR400085-3; IP0IR400100-3; IP0IR400115-3; IP0IR400130-3; IP0IR400150-3; IP0IR400180-3; IP4IE500085; IP4IE500100; IP4IE500115/IP4IE500130; IP4IE500150; IP4IE430085; IP4IE430100; IP4IE430115; IP4IE430130; IP4IE430150; IP5ER400070-2; IP5ER400085-2; IP5ER400100-2; IP5ER400115-2; IP5ER400130-2; IP5ER400150-2; IP5ER400180-2; IP5ER400070-3; IP5ER400085-3; IP5ER400100-3; IP5ER400115-3; IP5ER400130-3; IP5ER400150-3; IP5ER400180-3; IP5IR400070-2; IP5IR400085-2; IP5IR400100-2; IP5IR400115-2; IP5IR400130-2; IP5IR400150-2; IP5IR400180-2; IP5IR400070-3; IP5IR400085-3; IP5IR400100-3; IP5IR400115-3; IP5IR400130-3; IP5IR400150-3; IP5IR400180-3; IP3ER400070L; IP3ER400085L; IP3ER400100L; IP3ER400115L; IP3ER400130L; IP3ER400150L; IP3ER400180L; IP3EA500070L; IP3EA500085L; IP3EA500100L; IP3EA500115L; IP3EA500130L; IP3EA500150L; IP3EA500180L; IP3IE350070L; IP3IE350085L; IP3IE350100L; IP3IE350115L; IP3IE350130L; IP3IE350150L; IP3IE350180L; IP3IR400070L; IP3IR400085L; IP3IR400100L; IP3IR400115L; IP3IR400130L; IP3IR400150L; IP3IR400180L; IP3IR500070L; IP3IR 500085L; IP3IR500100L; IP3IR500115L; IP3IR500130L; IP3IR500150L; IP3IR500180L; IP4IE500085L; IP4IE500100L; IP4IE500115L; IP4IE500130L; IP4IE500150L; IP4IE430085L; IP4IE430100L; IP4IE430115L; IP4IE430130L; IP4IE430150L; IP5ER400070-2L; IP5ER400085-2L; IP5ER400100-2L; IP5ER400115-2L; IP5ER400130-2L; IP5ER400150-2L; IP5ER400180-2L; IP5ER400070-3L; IP5ER400085-3L; IP5ER400100-3L; IP5ER400115-3L; IP5ER400130-3L; IP5ER400150-3L; IP5ER400180-3L; IP5IR400070-2L; IP5IR400085-2L; IP5IR400100-2L; IP5IR400115-2L; IP5IR400130-2L; IP5IR400150-2L; IP5IR400180-2L; IP5IR400070-3L; IP5IR400085-3L; IP5IR400100-3L; IP5IR400115-3L; IP5IR400130-3L; IP5IR400150-3L; IP5IR400180-3L.**
Marca/Marche: Trade mark(s):	**FUSIO**

Allegato al Certificato CE n. 1363/MDD- Elenco dei Dispositivi

Annex of EC Certificate no. 1363/MDD - Device List

rev. 1 del/of **2020/12/17**

Categoria di dispositivo: Device category:	**Micro impianti** Micro implant
Modello/i: Model(s):	**MI140060; MI140080; MI140100; MI160060; MI160080; MI160100, MI200060; MI200080; MI200100.**
Marca/Marche: Trade mark(s):	./.

Categoria di dispositivo: Device category:	**Frese dentali** Dental drills
Modello/i: Model(s):	**F15013; F20016; FH42; FH50; FEE232816; FEE283216; FEE323616; FEE364216; FTE35150; FTR40180; FTA50150; FTR40068; FTA50037; FTIE35075; FTIR40068; FTE35320; FTE35400; FTE40320; FTE40400; FTE50320; FTE50400.**
Marca/Marche: Trade mark(s):	./.

Categoria di dispositivo: Device category:	**Perno di fissaggio** Fixing pin
Modello/i: Model(s):	**CHTL10350 ; CHTL10450 ; CHTL10550 ; CHTL10650**
Marca/Marche: Trade mark(s):	./.

Categoria di dispositivo: Device category:	**Mini vite di fissaggio** Mini fixing screw
Modello/i: Model(s):	**CHTR12040; CHTR12050; CHTR12060; CHTR12070; CHTR12080; CHTR12090; CHTR12100; CHTR12110; CHTR12120; CHTR15040; CHTR15050; CHTR15060; CHTR15070; CHTR15080; CHTR15090; CHTR15100; CHTR15110; CHTR15120; CHTR15130; CHTR15150; CHTR20040; CHTR20050; CHTR20060; CHTR20070; CHTR20080; CHTR20090; CHTR20100; CHTR20110; CHTR20120; CHTR20130; CHTR20150; CHTR20170; CHTR20190; CHTC20040; CHTC20050; CHTC20060.**
Marca/Marche: Trade mark(s):	./.