

Certificato di conformità CE

EC Certificate of Conformity



**Sistema completo di garanzia di qualità secondo direttiva 93/42/CEE allegato II escluso punto 4
EC Directive 93/42/EEC Annex II, excluded clause 4 Full Quality Assurance System Medical Devices**

Certificato n°: HD 60130544

Registration No:

Fabbricante: Dr. Ihde Dental AG
Manufacturer:

Sede legale e operativa: **Dorfplatz, 11**
Registered and Operational **8737 Gommiswald – Switzerland**
Headquarter:

Scopo: Impianti dentali / Dental implants

Scope:

**Strumenti ed attrezzature dentali non attivi / Non-active dental
equipment and instruments**

(Vedere allegato tecnico al presente Certificato per tipologie, modelli e codici)
(See the attachment for typologies, models and codes designation)

L'organismo notificato dichiara che il Sistema di qualità stabilito ed applicato dalla società sopra specificata soddisfa i requisiti dell'allegato II, articolo 3 della suddetta direttiva. Questa approvazione è soggetta a sorveglianza periodica, così come definita nell'allegato II, articolo 5 della suddetta direttiva e può essere utilizzata congiuntamente alla dichiarazione di conformità redatta dal fabbricante. / The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5, of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

L'organismo notificato/ Notified Body

Data di emissione/Issue date: 26/06/2018

Data di ultima modifica/Last revision date: 28/07/2020

Data di scadenza/Expiry date: 29/11/2022



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TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)
Autorizzata dal Ministero della Salute e dal Ministero dello Sviluppo Economico
Accredited by Ministry of Health and by Ministry of Economic Development

Organismo notificato con il numero 1936 presso la Commissione Europea
Notified under No. 1936 to the EC Commission

CE La marcatura CE può essere apposta esclusivamente se vengono soddisfatti i requisiti di tutte le direttive CE applicabili **CE**
The CE marking may be used if all relevant and effective EC Directives are complied with

Fabbricante/Manufacturer: Dr. Ihde Dental AG

Scopo/Scope: Impianti dentali / Dental implants

Tipologia/ Typology: Two-Part Implants

Marca/ Brand name:

Dr. Ihde Dental AG

Modello/ Model:

**HC2 (Hexacone); HC 6+2 (Hexacone 6+2); HC2 PLUS MU (Hexacone Plus MU); TPG;
SSO/STO/STW; BLP (Bone Level Plus); Xi (Xign)**

Marca/ Brand name:

OneWay Biomed

Modello/ Model:

GIH2, GIH PLUS MU, GIO/STO/STW, GBL, GXi

Tipologia/ Typology: Single Piece Implants

Marca/ Brand name:

Dr. Ihde Dental AG

Modello/ Model:

**BCS; BCS MU; ZSI; ZSI MU; KOS M; KOS MICRO; KOS MICRO-D; KOS; KOS ROOT;
Classic Root; KOS X; KOS K; KOS B; KOS TX; KOS MU; TPG UNO; TPG UNO SH;
KDS**

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Allegato tecnico al Certificato n° HD 60130544
Attachment to the certificate:



Marca/ Brand name:

OneWay Biomed

Modello/ Model:

**GBC; GBC MU; GZI; GCS M; GCS MICRO; GCS; GCS ROOT; GCS X; GCS K; GCS B;
GCS TX; GCS MU; GPG one**

Tipologia/ Typology: Abutments

Marca/ Brand name:

Dr. Ihde Dental AG

Modello/ Model:

**TCA; TCA W; TLA HC; TLAS; TLA HC2; TLA HC4; TLA W; TLA 15 HC1; TLA 15 HC2;
TLA 15 HC3; TLA 25 HC1; TLA 25 HC2; TLA 25 HC3; ANAB; TSA 3; TSA 4; TSA 5;
TSA 6; PSTR; PSTA; HRA HC; MU2 17 HC; MU2 35 HC; MU2S 0.5 HC; MU2S 1.5 HC;
MU2S 2.5 HC; SB; TB 0.5; TB 2; TB 4; MB HC; MBR HC; TPB 3 HC; TLA STI; TLA 15
STI; TLA 20 STI; TLA 25 STI; TCA STI; OF 4 STI; OF 48 STI; OF 5 STI; OF 5L STI;
CAB 1 NC; CAB 1 RC; CAB 3 NC; CAB 3 RC; TAB BLP NC/RC; TLA2 15 BLP NC;
TLA2 15 BLP RC; ANAB NC; ANAB RC; PLAB BLP NC; PLAB BLP RC; TCT BLP RC
0.5; TCT BLP RC 1.5; TCT BLP RC 3.5; TCT BLP NC 0.5; TCT BLP NC 1.5; TCT BLP
NC 3.5; MU2 17 BLP RC; MU2 35 BLP RC; MU2S 0.5 BLP RC; MU2S 1.5 BLP RC;
MU2S 2.5 BLP RC; TLA STO; TLA 15 STO; TLA 15F STO; TLA 20 STO; TLA 25 STO;
TLA 25F STO; TCA STI; SA4 STI; SA5 STI; SA4 STI; TCA4 STI; TCA5 STI; TCA4 STI;
OSA STO; OSA STI; TCT SSO 0.5; TCT SSO 1.5; TCT SSO 2.5; TCT SSO 4; LOC S
2.5; LOC S 4; TB STI; TB2 STI; TB3 STI; TLA STW; TLA 15 STW; SA4 STW; SA6
STW; TB STW; TB3 STW; TLA Xi 3.0 2; TLA Xi 3.0 3; TLA Xi 3.0 5; TLA Xi 3.4 1; TLA
Xi 3.4 2; TLA Xi 3.4 3; TLA Xi 3.4 5; TLA Xi 3.4 8; TLA Xi 3.8 1; TLA Xi 3.8 2; TLA Xi
3.8 3; TLA Xi 3.8 5; TLA Xi 4.5 1; TLA Xi 4.5 2; TLA Xi 4.5 3; TLA 15; Xi 3.4 1; TLA 15
Xi 3.4 2; TLA 15 Xi 3.4 3; TLA 15 Xi 3.8 1; TLA 15 Xi 3.8 2; TLA 15 Xi 3.8 4; TLA 15 Xi
4.5 1; TLA 15 Xi 4.5 2; TLA 15 Xi 4.5 4; TLA 25 Xi 3.4 1; TLA 25 Xi 3.4 2; TLA 25 Xi 3.4
3; TLA 25 Xi 3.8 1; TLA 25 Xi 3.8 2; TLA 25 Xi 3.8 3; TLA 25 Xi 3.8 4; TLA 25 Xi 4.5 1;
TLA 25 Xi 4.5 2; TLA 25 Xi 4.5 4; PA Xi; MB Xi 3.0; MB Xi 3.4; MB Xi 3.8; MB Xi 4.5;
OSA Xi 3.4 2; OSA Xi 3.8 2; OSA Xi 3.8 4; OSA Xi 4.5 2; TB Xi 3.0 2; TB Xi 3.0 4; TB Xi
3.4 2; TB Xi 3.4 4; TB Xi 3.8 2; TB Xi 3.8 4; TB Xi 4.5 2; TB Xi 4.5 4; MU2 17 Xi 3.8;
MU2 35 Xi 3.8; MU2S 0.5 Xi 3.8; MU2S 1.5 Xi 3.8; MU2S 2.5 Xi 3.8;**



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Marca/ Brand name:

Oneway Biomed

Modello/ Model:

TCA; TCA W; TLA HC; TLAS; TLA HC2; TLA HC4; TLA W; TLA 15 HC1; TLA 15 HC2; TLA 15 HC3; TLA 25 HC1; TLA 25 HC2; TLA 25 HC3; ANAB; TSA 3; TSA 4; TSA 5; TSA 6; PSTR; PSTA; HRA HC; MU2 17 HC; MU2 35 HC; MU2S 0.5 HC; MU2S 1.5 HC; MU2S 2.5 HC; SB; TB 0.5; TB 2; TB 4; MB HC; MBR HC; TPB 3 HC; TLA STI; TLA 15 STI; TLA 20 STI; TLA 25 STI; TCA STI; OF 4 STI; OF 48 STI; OF 5 STI; OF 5L STI; CAB 1 NC; CAB 1 RC; CAB 3 NC; CAB 3 RC; TAB BLP NC/RC; TLA2 15 BLP NC; TLA2 15 BLP RC; ANAB NC; ANAB RC; PLAB BLP NC; PLAB BLP RC; TCT BLP RC 0.5; TCT BLP RC 1.5; TCT BLP RC 3.5; TCT BLP NC 0.5; TCT BLP NC 1.5; TCT BLP NC 3.5; MU2 17 BLP RC; MU2 35 BLP RC; MU2S 0.5 BLP RC; MU2S 1.5 BLP RC; MU2S 2.5 BLP RC; TLA STO; TLA 15 STO; TLA 15F STO; TLA 20 STO; TLA 25 STO; TLA 25F STO; TCA STI; SA4 STI; SA5 STI; SA4 STI; TCA4 STI; TCA5 STI; TCA4 STI; OSA STO; OSA STI; TCT SSO 0.5; TCT SSO 1.5; TCT SSO 2.5; TCT SSO 4; LOC S 2.5; LOC S 4; TB STI; TB2 STI; TB3 STI; TLA STW; TLA 15 STW; SA4 STW; SA6 STW; TB STW; TB3 STW; TLA Xi 3.0 2; TLA Xi 3.0 3; TLA Xi 3.0 5; TLA Xi 3.4 1; TLA Xi 3.4 2; TLA Xi 3.4 3; TLA Xi 3.4 5; TLA Xi 3.4 8; TLA Xi 3.8 1; TLA Xi 3.8 2; TLA Xi 3.8 3; TLA Xi 3.8 5; TLA Xi 4.5 1; TLA Xi 4.5 2; TLA Xi 4.5 3; TLA 15; Xi 3.4 1; TLA 15 Xi 3.4 2; TLA 15 Xi 3.4 3; TLA 15 Xi 3.8 1; TLA 15 Xi 3.8 2; TLA 15 Xi 3.8 4; TLA 15 Xi 4.5 1; TLA 15 Xi 4.5 2; TLA 15 Xi 4.5 4; TLA 25 Xi 3.4 1; TLA 25 Xi 3.4 2; TLA 25 Xi 3.4 3; TLA 25 Xi 3.8 1; TLA 25 Xi 3.8 2; TLA 25 Xi 3.8 3; TLA 25 Xi 3.8 4; TLA 25 Xi 4.5 1; TLA 25 Xi 4.5 2; TLA 25 Xi 4.5 4; PA Xi; MB Xi 3.0; MB Xi 3.4; MB Xi 3.8; MB Xi 4.5; OSA Xi 3.4 2; OSA Xi 3.8 2; OSA Xi 3.8 4; OSA Xi 4.5 2; TB Xi 3.0 2; TB Xi 3.0 4; TB Xi 3.4 2; TB Xi 3.4 4; TB Xi 3.8 2; TB Xi 3.8 4; TB Xi 4.5 2; TB Xi 4.5 4; MU2 17 Xi 3.8; MU2 35 Xi 3.8; MU2S 0.5 Xi 3.8; MU2S 1.5 Xi 3.8; MU2S 2.5 Xi 3.8;

Tipologia/ Typology: **Adapters**

Marca/ Brand name:

Dr. Ihde Dental AG

Modello/ Model:

AA15 KK; AA25 KK; AA5 15°; AA5 25°; ZAA15 KK; ZAA25 KK; B21; B21 ANA

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Marca/ Brand name:

Oneway Biomed

Modello/ Model:

AA15 KK; AA25 KK; AA5 15°; AA5 25°; ZAA15 KK; ZAA25 KK; B21; B21 ANA

Scopo/Scope: Strumenti ed attrezzature dentali non attivi / Non-active dental equipment and instruments

Tipologia/ Typology: Surgical Drills

Marca/ Brand name:

Dr. Ihde Dental AG

Modello/ Model:

BCD 1; BCD 2; BCD 3; BCDX 1; BCDX 2; BCDX 3; Twist Drill 1.8/23; 2.0/21; Twist Drill 2.0/30; Twist Drill 2.0/40; Twist Drill 2.5/21; Twist Drill 2.0 cylindrical; Twist Drill 2.5 cylindrical; Twist Drill 2.2/50; Twist Drill 2.2/55; Twist Drill 2.5/21; C-Drill KM1; C-Drill KM2; C-Drill KM3; C Drill Xi 3.0; C Drill 3.4; C Drill 3.7; C Drill 4.1; C Drill 4.2 – 4.5; C Drill 5.5; DRK 1; DRK 2; DRK 3; DRK 4; DRK 5; DRK 6; DOS 1; DOS 2; DOS 3; DOS 4; DOS 5; DOS 6; Drill 1.3 mm diameter; Drill 1.9 mm diameter; Drill 2.3 mm diameter; DFN 2.9 13; DFN 2.9 15; DS 2; DS 2.2; DS 2.8; DS 3.2; DS 3.5; DS 4.0; 4.2; DSL 2; DSL 2.2; DSL 2.8; DSL+ 2.8; DSL 3.2; DSL 3.5; DSL 4.0; DSL 4.2; DFN 3.0; DFN 3.4; DFN 3.7; DFN 4.1; DFN 4.2 - 4.5; DFN 5.5; DFLN 3.0; DFLN 3.4; DFLN+ 3.4; DFLN 3.7; DFLN 4.2 - 4.5; DFSN 3.7; DFSN 4.2 – 4.5; DBL 2.8; DBL 3.5; DBL 4.0; SHMC L; SHMC S

Marca/ Brand name:

Oneway Biomed

Modello/ Model:

BCD 1; BCD 2; BCD 3; BCDX 1; BCDX 2; BCDX 3; Twist Drill 1.8/23; 2.0/21; Twist Drill 2.0/30; Twist Drill 2.0/40; Twist Drill 2.5/21; Twist Drill 2.0 cylindrical; Twist Drill

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2.5 cylindrical; Twist Drill 2.2/50; Twist Drill 2.2/55; Twist Drill 2.5/21; C-Drill KM1; C-Drill KM2; C-Drill KM3; C Drill Xi 3.0; C Drill 3.4; C Drill 3.7; C Drill 4.1; C Drill 4.2 – 4.5; C Drill 5.5; DRK 1; DRK 2; DRK 3; DRK 4; DRK 5; DRK 6; DOS 1; DOS 2; DOS 3; DOS 4; DOS 5; DOS 6; Drill 1.3 mm diameter; Drill 1.9 mm diameter; Drill 2.3 mm diameter; DFN 2.9 13; DFN 2.9 15; DS 2; DS 2.2; DS 2.8; DS 3.2; DS 3.5; DS 4.0; 4.2; DSL 2; DSL 2.2; DSL 2.8; DSL+ 2.8; DSL 3.2; DSL 3.5; DSL 4.0; DSL 4.2; DFN 3.0; DFN 3.4; DFN 3.7; DFN 4.1; DFN 4.2 - 4.5; DFN 5.5; DFLN 3.0; DFLN 3.4; DFLN+ 3.4; DFLN 3.7; DFLN 4.2 - 4.5; DFSN 3.7; DFSN 4.2 – 4.5; DBL 2.8; DBL 3.5; DBL 4.0; SHMC L; SHMC S

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