

To whom it my concern
Gommiswald, 28.03.2023

Declaration concerning CE Certificate Nr. HD 60130544

According to the Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023, amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices,

Certificates issued by notified bodies in accordance with Directive 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have expired before 20 March 2023 shall be considered to be valid until:

- 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;
- 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function

if before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;

Ihde Dental AG declares that the conditions for the extension are fulfilled, as:

- Directive 93/42/EEC certificate (HD 60130544, expiring on 29 November 2022 issued by TUV Rheinland Italia) shall be considered valid.
- Ihde Dental AG has a written agreement with the Notified Body TÜV Rheinland Italia. Specifically, the contract nr. 72362399 was issued on 03.12.2021 for the Medical Device Regulation conformity assessment in respect of the following devices:

SINGLE PIECE IMPLANTS, TWO-PART IMPLANTS,
SURGICAL DRILLS, ABUTMENTS&ADAPTERS

Furthermore, Ihde Dental AG complies to art. 120(3c) requirements:

- a) The abovementioned devices continue to comply with Directive 93/42/EEC;
- b) there are no significant changes in the design and intended purpose;
- c) the abovementioned devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- d) the manufacturer has put in place a quality management system in accordance with Article 10(9);

Therefore, HD 60130544 certificate shall be considered valid until:

- 31 December 2027 for SINGLE PIECE IMPLANTS, TWO-PART IMPLANTS, ABUTMENTS&ADAPTERS being class IIb implantable devices.
- 31 December 2028 for SURGICAL DRILLS being class IIa devices

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:
Registered and Operational
Headquarter: **Dorfplatz, 11**
8737 Gommiswald – Switzerland

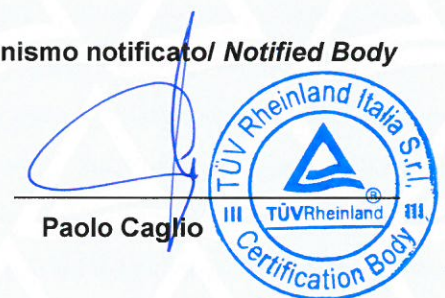
Scopo: **Impianti dentali / Dental implants**
Scope: **Strumenti ed attrezzature dentali non attivi / Non-active dental**
equipment and instruments

(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: 25/05/2021
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); HC 6+2 (Hexacone 6+2); HC 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;
KOS Mini; KOS Plus**

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L'organismo notificato
Notified Body



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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; GCS Mini; GCS Plus**

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; 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; 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; Kugeladapter

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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;
Kugeladapter**

**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 1 Adapter; 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; KDS**

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Marca/ Brand name:

Oneway Biomed

Modello/ Model:

BCD 1; BCD 1 Adapter; 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; KDS

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