

# EU Declaration of Conformity EU-Konformitätserklärung



We / Wir

**W&H DENTALWERK BÜRMOOS GmbH**  
Ignaz-Glaser-Straße 53  
A-5111 Bürmoos / Österreich  
SRN: AT-MF-000001590

declare under our sole responsibility, that the products  
erklären in alleiniger Verantwortung, dass die Produkte

**Instrument / Instrument / Instrumento**  
**Basic UDI-DI: ++J021S0003R6**  
*According to page 2 / gemäß Seite 2 / Conforme al pagina 2*

to which this declaration relates, fulfil the requirements of the **Regulation (EU) 2017/745 (Medical Devices)**.  
auf die sich diese Erklärung bezieht, den Anforderungen der **Verordnung (EU) 2017/745 (Medizinprodukte)**,  
entsprechen.

Class / Klasse: **IIa**

Rule / Regel: **6.1.**

Conformity assessment procedure / Konformitätsbewertungsverfahren: **Annex / Anhang: IX Kap. I**

Notified Body / Benannte Stelle:

**DQS Medizinprodukte GmbH**  
**August-Schanz-Straße 21**  
**D-60433 Frankfurt/Main**  
**0297**

Identification no. / Kennnummer:

004911MDR2017Q Certificate unique ID:

1000153568

## Intended use / Zweckbestimmung:

Instruments for use with Surgical Piezo-Scaler for the following dental applications and for applications in Cranio-  
Maxillo-Facial surgery (CMF): / Instrumente für die Verwendung mit Piezo-Chirurgiescaler für folgende dentale  
Anwendungen und für Anwendungen in der Mund-, Kiefer- und Gesichtschirurgie (MKG):

- Bone treatment Instruments and Instrument set "bone" / Knochenbearbeitungs-Instrumente und Instrumentenset "Bone": B1, B2R, B2L, B3, B5, B4, B6, B7.
- Periodontal Instruments and Instrument set "paro" / Parodontal-Instrumente und Instrumentenset "Paro": P1, P2RD, P2LD.
- Extraction Instruments and Instrument set "EX": / Extraktions-Instrumente und Instrumentenset: "EX" / EX1, EX2.
- Endodontie-Instrumente und Instrumentenset "Endo" / Endodontic Instruments and Instrument set "Endo": R1D, R2RD, R2LD, R3D, R4RD, R4LD.
- Sinus-Instrumente und Instrumentenset "Special" / Sinus Instruments and Instrument set "Special": S1, S2, S3, S4, S5.
- Vertical sinus lift Instruments and Instrument set "Implant/Crestal A", Instrument set "Implant/Crestal P": / Vertikaler Sinuslift Instrumente und Instrumentenset "Implant/Crestal A", Instrumentenset "Implant/Crestal P": Z25P, Z35P.
- Implantology Instruments and Instrument set "Implant/Crestal A", Instrument set "Implant/Crestal P": / Implantologie Instrumente und Instrumentenset "Implant/Crestal A", Instrumentenset "Implant/Crestal P": I1, I2A, I2P, I3A, I3P, I4A, I4P.

Expiry date / gültig bis:

02.03.2027

In the case of significant changes to the products, the declaration of conformity loses its validity.  
Bei signifikanten Änderungen der Produkte verliert die Konformitätserklärung ihre Gültigkeit.

Bürmoos, 16.02.2024

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**Dipl.-Ing. Jürgen Weiss**  
**Geschäftsleitung/Management**  
**Person Responsible for Regulatory Compliance (PRRC)**

<b>Description / Bezeichnung / Descripción</b>	<b>Type/Typ</b>	<b>REF</b>
Instrument / Instrument / Instrumento	-	07173100
Instrument / Instrument / Instrumento	-	07173200
Instrument / Instrument / Instrumento	-	07173300
Instrument / Instrument / Instrumento	-	07173400
Instrument / Instrument / Instrumento	-	07173500
Instrument / Instrument / Instrumento	-	07997090
Instrument / Instrument / Instrumento	-	07997110
Instrument / Instrument / Instrumento	B1	05530100
Instrument / Instrument / Instrumento	B2L	05544400
Instrument / Instrument / Instrumento	B2R	06958600
Instrument / Instrument / Instrumento	B3	05542100
Instrument / Instrument / Instrumento	B4	05543800
Instrument / Instrument / Instrumento	B5	05534500
Instrument / Instrument / Instrumento	B6	07022500
Instrument / Instrument / Instrumento	B7	07022600
Instrument / Instrument / Instrumento	EX1	06069300
Instrument / Instrument / Instrumento	EX2	06071100
Instrument / Instrument / Instrumento	I1	07786800
Instrument / Instrument / Instrumento	I2A	07797800
Instrument / Instrument / Instrumento	I2P	07788800
Instrument / Instrument / Instrumento	I3A	07885600
Instrument / Instrument / Instrumento	I3P	07887000
Instrument / Instrument / Instrumento	I4A	07889400
Instrument / Instrument / Instrumento	I4P	07889500
Instrument / Instrument / Instrumento	P1	06067700
Instrument / Instrument / Instrumento	P2LD	06061800
Instrument / Instrument / Instrumento	P2RD	06061700
Instrument / Instrument / Instrumento	R1D	05975200
Instrument / Instrument / Instrumento	R2LD	05999400
Instrument / Instrument / Instrumento	R2RD	05991000
Instrument / Instrument / Instrumento	R3D	05998800
Instrument / Instrument / Instrumento	R4LD	06004700
Instrument / Instrument / Instrumento	R4RD	06005000
Instrument / Instrument / Instrumento	S1	05542900
Instrument / Instrument / Instrumento	S2	05534700
Instrument / Instrument / Instrumento	S3	05508200
Instrument / Instrument / Instrumento	S4	05542300
Instrument / Instrument / Instrumento	S5	05542800
Instrument / Instrument / Instrumento	Z25P	07785600
Instrument / Instrument / Instrumento	Z35P	07980600