

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

Turbine handpiece / Turbine / Turbina

Basic UDI-DI: ++J021RP0001Q8

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)**,
2006/42/EC (Machinery) and 2011/65/EU (RoHS)*.

auf die sich diese Erklärung bezieht, den Anforderungen der **Verordnung (EU) 2017/745 (Medizinprodukte)**,
2006/42/EG (Maschinen) und 2011/65/EU (RoHS)* entsprechen.

Class / Klasse: **Ila**

Rule / Regel: **9.1.**

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:

004911MDR2017B Certificate unique ID (Product):
004911MDR2017Q Certificate unique ID (QMS):

1000137995
1000138002

Intended use / Zweckbestimmung:

The dental turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces./

Die Dentalturbine ist für folgende Anwendungen bestimmt: Entfernung kariösen Materials, Kavitäten- und Kronenpräparation, Entfernung von Füllungen, finieren von Zahn- und Restaurationsoberflächen.

*RoHS: without involvement of the notified body / ohne Einbezug des Notified Body

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, 27.11.2023

Dipl.-Ing. Jürgen Weiss
Standortleitung / Site Leadership
Person Responsible for Regulatory Compliance (PRRC)

Description / Bezeichnung / Descripción	Type/Typ	REF
Turbine handpiece / Turbine / Turbina	RC-90 BC	11049000
Turbine handpiece / Turbine / Turbina	RC-90 RM	11049001
Turbine handpiece / Turbine / Turbina	RC-95 BC	11049500
Turbine handpiece / Turbine / Turbina	RC-95 RM	11049501
Turbine handpiece / Turbine / Turbina	RC-98 BC	30385000
Turbine handpiece / Turbine / Turbina	RC-98 RM	30384000
Turbine handpiece / Turbine / Turbina	RG-97 L	30222000
Turbine handpiece / Turbine / Turbina	RK-97 L	30221000
Turbine handpiece / Turbine / Turbina	TE-95 BC	30074000
Turbine handpiece / Turbine / Turbina	TE-95 RM	30075000
Turbine handpiece / Turbine / Turbina	TE-97	30068000
Turbine handpiece / Turbine / Turbina	TE-97	30068001
Turbine handpiece / Turbine / Turbina	TE-97 BC	30069000
Turbine handpiece / Turbine / Turbina	TE-97 LQ	30066000
Turbine handpiece / Turbine / Turbina	TE-97 LQ	30066001
Turbine handpiece / Turbine / Turbina	TE-97 RM	30070000
Turbine handpiece / Turbine / Turbina	TE-97 RM	30070001
Turbine handpiece / Turbine / Turbina	TE-98	30071000
Turbine handpiece / Turbine / Turbina	TE-98	30071001
Turbine handpiece / Turbine / Turbina	TE-98 BC	30072000
Turbine handpiece / Turbine / Turbina	TE-98 LQ	30067000
Turbine handpiece / Turbine / Turbina	TE-98 LQ	30067001
Turbine handpiece / Turbine / Turbina	TE-98 RM	30073000
Turbine handpiece / Turbine / Turbina	TG-97	30005000
Turbine handpiece / Turbine / Turbina	TG-97	30005002
Turbine handpiece / Turbine / Turbina	TG-97 L	30004000
Turbine handpiece / Turbine / Turbina	TG-97 L	30004002
Turbine handpiece / Turbine / Turbina	TG-97 L	30004003
Turbine handpiece / Turbine / Turbina	TG-97 L N	30199000
Turbine handpiece / Turbine / Turbina	TG-97 L N	30199001
Turbine handpiece / Turbine / Turbina	TG-97 L RM	30197000
Turbine handpiece / Turbine / Turbina	TG-97 LM	30006000
Turbine handpiece / Turbine / Turbina	TG-97 LM	30006002
Turbine handpiece / Turbine / Turbina	TG-97 LW	30201000
Turbine handpiece / Turbine / Turbina	TG-97 LW	30201001
Turbine handpiece / Turbine / Turbina	TG-98	30002000
Turbine handpiece / Turbine / Turbina	TG-98	30002002
Turbine handpiece / Turbine / Turbina	TG-98 L	30001000
Turbine handpiece / Turbine / Turbina	TG-98 L	30001002
Turbine handpiece / Turbine / Turbina	TG-98 L	30001003
Turbine handpiece / Turbine / Turbina	TG-98 L N	30200000
Turbine handpiece / Turbine / Turbina	TG-98 L N	30200001

Turbine handpiece / Turbine / Turbina	TG-98 L RM	30198000
Turbine handpiece / Turbine / Turbina	TG-98 LM	30003000
Turbine handpiece / Turbine / Turbina	TG-98 LM	30003002
Turbine handpiece / Turbine / Turbina	TG-98 LW	30202000
Turbine handpiece / Turbine / Turbina	TG-98 LW	30202001
Turbine handpiece / Turbine / Turbina	TK-100 L	30021000
Turbine handpiece / Turbine / Turbina	TK-100 L	30021001
Turbine handpiece / Turbine / Turbina	TK-100 LM	30022000
Turbine handpiece / Turbine / Turbina	TK-94 L	30016001
Turbine handpiece / Turbine / Turbina	TK-94 L	30016000
Turbine handpiece / Turbine / Turbina	TK-94 LM	30031000
Turbine handpiece / Turbine / Turbina	TK-97 L	30017000
Turbine handpiece / Turbine / Turbina	TK-97 L	30017001
Turbine handpiece / Turbine / Turbina	TK-97 LM	30018000
Turbine handpiece / Turbine / Turbina	TK-98 L	30019000
Turbine handpiece / Turbine / Turbina	TK-98 L	30019001
Turbine handpiece / Turbine / Turbina	TK-98 LM	30020000