



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

W & H Dentalwerk Bürmoos GmbH

Ignaz-Glaser-Straße 53
5111 Bürmoos
Austria

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Active dental equipment and accessories, active surgical equipment and accessories according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	004911 MR2
Certificate unique ID	170764041
Effective date	2020-02-08
Expiry date	2023-08-02
Frankfurt am Main	2020-02-08

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
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Device family	Device	Class
Dental handpieces: Restoration and Prosthetic	Turbine handpieces and adapters, dental Straight and contra-angle handpieces, dental	IIa
Dental handpieces: Endodontics	ENDO Cursor, ENDO Niti and Endea, contra-angle handpieces, Entran Cordless	IIa
Dental handpieces: Scaler	Air Scaler, Piezo scaler, Scaler tips	IIa
Dental handpieces: Prophylaxis and Periodontology	Profin contra-angle handpieces, Prophy and Proxeo straight and contra-angle handpieces	IIa
Dental handpieces: Injectors	Injection handpiece	IIa
Surgical instruments	Straight and contra-angle handpieces, surgery, Saw handpieces, Right-angled screwdrivers	IIa
Driving, control and supply systems	Air motors, Electric motors, Control units, Supply hoses / - lines, Footcontrol	IIa
Couplings	ROTO QUICK	IIa
Surgical units with accessories	elcoMED, implantMED, Piezomed, Osstell-module AMADEO	IIa