EU - DECLARATION OF CONFORMITY

EU - KONFORMITÄTSERKLÄRUNG

LEGAL MANUFACTURER NAME, ADDRESS Name und Adresse des Herstellers	VDW GmbH Bayerwaldstraße 15 81737 München / Munich Deutschland / Germany
SINGLE REGISTRATION NUMBER (SRN) Registrierungsnummer des Herstellers	DIMDI Registration Number: DE/0000029227
AUTHORIZED REPRESENTATIVE NAME, ADDRESS Name und Adresse des Repräsentanten	N/A
PRODUCT GROUP Produktgruppe	Size Tools
INTENDED PURPOSE Zweckbestimmung	Device intended for reporting the working length of endodontic instruments, gutta-percha points and absorbent points.

PRODUCT NAME / MD NOMENCLATURE
Produktbezeichnung / MP Nomenklatur

Product Name	*Brand Name*	*GMDN*	*UMDN*	*CND/EMDN*
Minifix Measuring Gauge	N/A	----	----	Q01010299

RISK CLASS Risikoklasse	Class I / Rule 1; non-sterile, re-usable
CATALOG (SKU) NUMBER OR BASIC UDI-DI Artikelnummer oder Basic UDI-DI	CATALOG (SKU) NUMBER: V040179 BASIC UDI-DI: ++E22510048DQ
COMMON SPECIFICATION Spezifikation	N/A
NOTIFIED BODY NAME Name der Benannten Stelle NOTIFIED BODY IDENTIFICATION NUMBER Identifikation der Benannten Stelle	TÜV SÜD Product Service GmbH Ridlerstr. 65 80339 München / Munich CE 0123
APPLICABLE EU LEGISLATIONS & CONFORMITY ASSESSMENT PROCEDURE Konformitätsbewertungsverfahren	☐ **MDD 93/42/EWG, Amendment 2007/47/EEC.** ☒ **MDR 2017/745** Acc. to Annex IX

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CERTIFICATE(S) ISSUED, Ausstellung des Zertifikats	Certificate No / Rev.: N/A
CERTIFICATE(S) VALIDITY DATE Gültigkeitsdatum des Zertifikats	N/A
TECHNICAL DOCUMENTATION DEMONSTRATING THE CONFORMITY TO THE ABOVE LEGISLATION'S REQUIREMENTS	Technical documentation for Working length tool (VDW) Document number 1000-TF_0_TDI_000035

STATEMENT OF DECLARATION
STELLUNGNAHME DER ERKLÄRUNG

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE APPLICABLE PROVISIONS OF THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NAME, TITLE, FUNCTION	Petra Altmann-Peichl, Director QA/RA
PLACE, DATE OF ISSUE	Munich, 25.05.2021
NAME, TITLE, FUNCTION	Ferdinand Engel, General Manager & Director Sales
PLACE, DATE OF ISSUE	Munich, 25.05.2021
VALIDITY DATE	Please see: CERTIFICATE(S) VALIDITY DATE
REV. Nr.	00

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