

DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

LEGAL MANUFACTURER NAME, ADDRESS <small>Name und Adresse des Herstellers</small>	VDW GmbH Bayerwaldstraße 15 81737 München / Munich Deutschland / Germany																					
SINGLE REGISTRATION NUMBER (SRN) <small>Registrierungsnummer des Herstellers</small>	DIMDI Registration Number: DE/0000029227																					
AUTHORIZED REPRESENTATIVE NAME, ADDRESS <small>Name und Adresse des Repräsentanten</small>	N/A																					
PRODUCT GROUP <small>Produktgruppe</small>	Sterile root canal instruments for single use																					
PRODUCT NAME / MD NOMENCLATURE <small>Produktbezeichnung / MP Nomenklatur</small>	<table border="0" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #f0f0f0;"> <th style="text-align: left; font-weight: normal;"><i>Product Name</i></th> <th style="text-align: left; font-weight: normal;"><i>GMDN</i></th> <th style="text-align: left; font-weight: normal;"><i>UMDN</i></th> </tr> </thead> <tbody> <tr> <td>VDW STERILE* Barbed Broaches</td> <td>63202</td> <td>10-521</td> </tr> <tr> <td>RECIPROC File</td> <td>40529</td> <td>10-521</td> </tr> <tr> <td>RECIPROC <i>blue</i> File</td> <td>40529</td> <td>10-521</td> </tr> <tr> <td>R-Pilot File</td> <td>40529</td> <td>10-521</td> </tr> <tr> <td>EDDY endo irrigation tip</td> <td>61639</td> <td>16-464</td> </tr> <tr> <td colspan="3">*available as non-sterile (ns) variant</td> </tr> </tbody> </table>	<i>Product Name</i>	<i>GMDN</i>	<i>UMDN</i>	VDW STERILE* Barbed Broaches	63202	10-521	RECIPROC File	40529	10-521	RECIPROC <i>blue</i> File	40529	10-521	R-Pilot File	40529	10-521	EDDY endo irrigation tip	61639	16-464	*available as non-sterile (ns) variant		
<i>Product Name</i>	<i>GMDN</i>	<i>UMDN</i>																				
VDW STERILE* Barbed Broaches	63202	10-521																				
RECIPROC File	40529	10-521																				
RECIPROC <i>blue</i> File	40529	10-521																				
R-Pilot File	40529	10-521																				
EDDY endo irrigation tip	61639	16-464																				
*available as non-sterile (ns) variant																						
RISK CLASS <small>Risikoklasse</small>	Class IIa / Rule 6																					
CATALOG (SKU) NUMBER OR BASIC UDI-DI <small>Artikelnummer oder Basic UDI-DI</small>	Please refer to PRODUCT LIST - ATTACHMENT																					
COMMON SPECIFICATION <small>Spezifikation</small>	R-Pilot: 1000-TF_0_TFDL_000009 V05/13 R-PILOT_Technical File Documents List (major version 6) Other instruments: Technical documentation is available as paper version on file																					
NOTIFIED BODY NAME <small>Name der Benannten Stelle</small>	TÜV SÜD Product Service GmbH Ridlerstr. 65 80339 München / Munich																					
NOTIFIED BODY IDENTIFICATION NUMBER <small>Identifikation der Benannten Stelle</small>	CE 0123																					

DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

APPLICABLE EU LEGISLATIONS & CONFORMITY ASSESSMENT PROCEDURE

Konformitätsbewertungsverfahren

CERTIFICATE(S) ISSUED,
Ausstellung des ZertifikatsCERTIFICATE(S) VALIDITY DATE
Gültigkeitsdatum des Zertifikats **MDD 93/42/EWG, Amendment 2007/47/EEC.**
Annex II – excluding Section 4 **MDR 2017/745**

Certificate No / Rev.: G1 015409 0035 Rev. 00

26.05.2024

STATEMENT OF DECLARATION

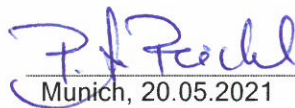
STELLUNGNAHME DER ERKLÄRUNG

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER AND CONFORMS TO ALL APPLICABLE REGULATIONS AND COMMON SPECIFICATION.

NAME, TITLE, FUNCTION

Petra Altmann-Peichl, Director QA/RA

PLACE, DATE OF ISSUE


Munich, 20.05.2021
BAYERWALDSTR. 15, 81737 MÜNCHEN
TEL. 089 / 6 27 34-0, FAX 089 / 6 27 34 - 304

VALIDITY DATE

Please see: CERTIFICATE(S) VALIDITY DATE

REV. Nr.

13

DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

PRODUCT LIST - ATTACHMENT:
 CATALOG(SKU) NUMBER OR BASIC UDI-DI (Artikelnummer oder Basic UDI-DI)

VDW STERILE Barbed Broaches

V040333021410	V040333021420	V040333021430	V040333021440	V040333021450
V040333021460	V040333021470	V040333021480	V040333021485	

ns variant:

V040033021410	V040033021420	V040033021430	V040033021440	V040033021450
V040033021460	V040033021470	V040033021480		

RECIPROC File

V040012021025	V040012021040	V040012021050	V040012021200	V040012025025
V040012025040	V040012025050	V040012025200	V040012031025	V040012031040
V040012031050	V040212021025	V040212021040	V040212021050	V040212021233
V040212025025	V040212025040	V040212025050	V040212025233	V040212031025
V040212031040	V040212031050	V040212031233		

RECIPROC *blue* File

V040052021025	V040052021040	V040052021050	V040052021200	V040052025025
V040052025040	V040052025050	V040052025200	V040052031025	V040052031040
V040052031050				
V040252021025	V040252021040	V040252021050	V040252025025	V040252025040
V040252025050	V040252031025	V040252031040	V040252031050	

R-Pilot File

V040017025012	V040217021012	V040217025012	V040217031012	V041217021012
V041217025012	V041217031012			

EDDY endo irrigation tip

V041441000000	V046034000000
---------------	---------------