DECLARATION OF CONFORMITY
KONFORMITÄTSERKLÄRUNG

LEGAL MANFACTURER 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	Rotating Root Canal Instruments

PRODUCT NAME / MD NOMENCLATURE
Produktbezeichnung / MP Nomenklatur

Product Name	*GMDN*	*UMDN*
Beutelrock Reamers	31823	10-521
Beutelrock Enlargers	31876	10-521
FlexMaster Files	40529	10-521
FlexMaster IntroFile	40529	10-521
Gates Enlargers	31876	10-521
GuttaMaster PrepiBurs	31823	15-569
Hedstroem File C.A.	40529	10-521
K-Reamers C.A.	31823	10-521
Kendo Gates Enlargers	31876	10-521
Kendo Root Fillers	41539	10-521
Mtwo Files	40529	10-521
Mtwo Retreatment Files	40529	10-521
Peeso Enlargers	31876	10-521
PRO-Endo Root Fillers	41539	10-521
PRO-Endo Peeso Enlargers	31876	10-521
PRO-Endo Gates Enlargers	31876	10-521
Root Filler "L"	41539	10-521
VDW.ROTATE Files	40529	10-521

RISK CLASS Risikoklasse	Class IIa / Rule 6
CATALOG (SKU) NUMBER OR BASIC UDI-DI Artikelnummer oder Basic UDI-DI	Please refer to PRODUCT LIST - ATTACHMENT
COMMON SPECIFICATION Spezifikation	VDW.ROTATE: 1000-TF_0_TFDL_000060 (major version 2): Endo-22 + Endo-27_Technical File Document List_VDW.ROTATE; Other products: The technical documentation is available as paper version on file

DECLARATION OF CONFORMITY
KONFORMITÄTSERKLÄRUNG

NOTIFIED BODY NAME Name der Benannten Stelle	TÜV SÜD Product Service GmbH Ridlerstr. 65 80339 München / Munich
NOTIFIED BODY IDENTIFICATION NUMBER Identifikation der Benannten Stelle	CE 0123
APPLICABLE EU LEGISLATIONS & CONFORMITY ASSESSMENT PROCEDURE Konformitätsbewertungsverfahren	☒ **MDD 93/42/EWG, Amendment 2007/47/EEC.** Annex II – excluding Section 4 ☐ **MDR 2017/745**
CERTIFICATE(S) ISSUED, Ausstellung des Zertifikats	Certificate No / Rev.: G1 015409 0035, Rev.00
CERTIFICATE(S) VALIDITY DATE Gültigkeitsdatum des Zertifikats	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
VALIDITY DATE	Please see: CERTIFICATE(S) VALIDITY DATE
REV. Nr.	32

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

DECLARATION OF CONFORMITY
KONFORMITÄTSERKLÄRUNG

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

Beutelrock Reamers (V01 - ANTAEOS, V02 - Beutelrock, V03 - Zipperer)				
V010944018001	V010944018002	V010944018003	V010944018004	V010944018005
V010944018006	V010944018300			
V020944018001	V020944018002	V020944018003	V020944018004	V020944018005
V020944018006	V020944018300			
V030944018001	V030944018002	V030944018003	V030944018004	V030944018005
V030944018006	V030944018300			
Beutelrock Enlargers (V01 - ANTAEOS, V02 - Beutelrock, V03 - Zipperer)				
V010947011001	V010947011002	V010947011003	V010947011004	V010947011005
V010947011006	V010947011300			
V020947011001	V020947011002	V020947011003	V020947011004	V020947011005
V020947011006	V020947011300			
V030947011001	V030947011002	V030947011003	V030947011004	V030947011005
V030947011006	V030947011300			
FlexMaster Files				
V040341021015	V040341021020	V040341021025	V040341021030	V040341021035
V040341021040	V040341021045	V040341021241	V040341025015	V040341025020
V040341025025	V040341025030	V040341025035	V040341025040	V040341025045
V040341025050	V040341025060	V040341025070	V040341025231	V040341031231
V040342021015	V040342021020	V040342021025	V040342021030	V040342021035
V040342021040	V040342025015	V040342025020	V040342025025	V040342025030
V040342025035	V040342025040	V040342031020	V040342031025	V040342031030
V040342031035	V040342031040	V040343021015	V040343021020	V040343021025
V040343021030	V040343021035	V040343021040	V040343025015	V040343025020
V040343025025	V040343025030	V040343025035	V040343025040	V040344025232
FlexMaster IntroFile				
V040357019000				
Gates Enlargers (V01 - ANTAEOS, V02 - Beutelrock, V03 - Zipperer, V04 - VDW)				
V010180019001	V010180019002	V010180019003	V010180019004	V010180019005
V010180019006	V010180019300			
V020180019001	V020180019002	V020180019003	V020180019004	V020180019005
V020180019006	V020180019300			
V030180019001	V030180019002	V030180019003	V030180019004	V030180019005
V030180019006	V030180019300			
V040380019001	V040380019002	V040380019003	V040380019004	V040380019005
V040380019006	V040380019300			
GuttaMaster PrepiBurs				
V040515000000				
Hedstroem File C.A (V01 - ANTAEOS, V02 - Beutelrock, V03 - Zipperer)				
V010078021010	V010078021015	V010078021020	V010078021025	V010078021030
V010078021035	V010078021040	V010078021230	V010078025010	V010078025015
V010078025020	V010078025025	V010078025030	V010078025035	V010078025040

DECLARATION OF CONFORMITY
KONFORMITÄTSERKLÄRUNG

V010078025045	V010078025050	V010078025055	V010078025060	V010078025070
V010078025080	V010078025230	V010078025240		
V020078021010	V020078021015	V020078021020	V020078021025	V020078021030
V020078021035	V020078021040	V020078021230	V020078025010	V020078025015
V020078025020	V020078025025	V020078025030	V020078025035	V020078025040
V020078025050	V020078025230	V020078025240		
V030078021010	V030078021015	V030078021020	V030078021025	V030078021030
V030078021035	V030078021040	V030078021230	V030078025010	V030078025015
V030078025020	V030078025025	V030078025030	V030078025035	V030078025040
K-Reamers C.A. (V01 - ANTAEOS, V02 - Beutelrock, V03 - Zipperer)				
V010058021008	V010058021010	V010058021015	V010058021020	V010058021025
V010058021030	V010058021035	V010058021040	V010058021045	V010058021050
V010058021055	V010058021060	V010058021070	V010058021080	V010058021220
V010058021230	V010058021240	V010058025008	V010058025010	V010058025015
V010058025020	V010058025025	V010058025030	V010058025035	V010058025040
V010058025045	V010058025050	V010058025055	V010058025060	V010058025070
V010058025080	V010058025220	V010058025230	V010058025240	
V020058021008	V020058021010	V020058021015	V020058021020	V020058021025
V020058021030	V020058021035	V020058021040	V020058021045	V020058021050
V020058021055	V020058021060	V020058021070	V020058021080	V020058021220
V020058021230	V020058021240	V020058025008	V020058025010	V020058025015
V020058025020	V020058025025	V020058025030	V020058025035	V020058025040
V020058025045	V020058025050	V020058025055	V020058025060	V020058025070
V020058025080	V020058025220	V020058025230	V020058025240	
V030058021008	V030058021010	V030058021015	V030058021020	V030058021025
V030058021030	V030058021035	V030058021040	V030058021220	V030058021230
V030058025010	V030058025015	V030058025025	V030058025030	V030058025220
V030058025230				
Kendo Gates Enlargers				
V200708019001	V200708019002	V200708019003	V200708019004	V200708019005
V200708019006	V200708019300			
Kendo Root Fillers				
V200709021025	V200709021030	V200709021035	V200709021040	V200709021290
V200709025025	V200709025030	V200709025035	V200709025040	V200709025290
Mtwo Files				
V040204021010	V040204021035	V040204021040	V040204021045	V040204021050
V040204021060	V040204025010	V040205021015	V040205021030	V040205025015
V040206021020	V040206021025	V040206021030	V040206021035	V040206021040
V040206025020	V040206025025	V040207021025	V040007021701	V040007021702
V040007025701	V040007025702	V040007025711	V040007031701	V040007031702
V040230021230	V040230021456	V040230021457	V040230025230	V040230025456
V040230025457	V040234021010	V040234021035	V040234021040	V040234021045
V040234021050	V040234021060	V040234025010	V040234025035	V040234025040
V040234025045	V040234025050	V040234025060	V040234025246	V040235021015
V040235021030	V040235025015	V040235025030	V040236021020	V040236021025
V040236021030	V040236021035	V040236021040	V040236025020	V040236025025
V040236025030	V040236025035	V040236025040	V040236025203	V040237021025
V040237025025	V041204025010	V041205025015	V041206025020	V041206025025
V041230025456	V041230025457	V041234025010	V041234031010	V041234031035
V041234031040	V041234031045	V041234031050	V041234031060	V041235025015
V041235031015	V041235031030	V041236025020	V041236025025	V041236031020
V041236031025	V041236031030	V041236031035	V041236031040	V041237031025

DECLARATION OF CONFORMITY
KONFORMITÄTSERKLÄRUNG

Mtwo Retreatment Files				
V040232021015	V040232021025	V040232021202		
Peeso Enlargers (V01 - ANTAEOS, V02 - Beutelrock, V03 - Zipperer)				
V010183019001	V010183019002	V010183019003	V010183019004	V010183019005
V010183019006	V010183019300			
V020183019001	V020183019002	V020183019003	V020183019004	V020183019005
V020183019006	V020183019300			
V030183019001	V030183019002	V030183019003	V030183019004	V030183019005
V030183019006	V030183019300			
PRO-Endo Root Fillers				
V200609021025	V200609021030	V200609021035	V200609021040	V200609021290
V200609025025	V200609025030	V200609025035	V200609025040	V200609025290
PRO-Endo Peeso Enlargers				
V200602019001	V200602019002	V200602019003	V200602019004	V200602019005
V200602019006	V200602019300			
PRO-Endo Gates Enlargers				
V200608019001	V200608019002	V200608019003	V200608019004	V200608019005
V200608019006	V200608019300			
Root Filler "L" (V01 - ANTAEOS, V02 - Beutelrock, V03 – Zipperer, V04 - VDW)				
V010093021025	V010093021030	V010093021035	V010093021040	V010093021290
V010093025025	V010093025030	V010093025035	V010093025040	V010093025290
V020093021025	V020093021030	V020093021035	V020093021040	V020093021290
V020093025025	V020093025030	V020093025035	V020093025040	V020093025290
V030093021025	V030093021030	V030093021035	V030093021040	V030093021290
V030093025025	V030093025030	V030093025035	V030093025040	V030093025290
V040393021025	V040393021030	V040393021035	V040393021040	V040393021290
V040393025025	V040393025030	V040393025035	V040393025040	V040393025290
VDW.ROTATE Files				
MSTVROT321AST	MSTVROT325AST	MSTVROT331AST	MSTVROT421415	MSTVROT421425
MSTVROT421430	MSTVROT421435	MSTVROT421440	MSTVROT421450	MSTVROT421460
MSTVROT421520	MSTVROT421525	MSTVROT421625	MSTVROT421630	MSTVROT421635
MSTVROT421640	MSTVROT425415	MSTVROT425425	MSTVROT425430	MSTVROT425435
MSTVROT425440	MSTVROT425450	MSTVROT425460	MSTVROT425520	MSTVROT425625
MSTVROT425630	MSTVROT425635	MSTVROT425640	MSTVROT431415	MSTVROT431425
MSTVROT431430	MSTVROT431435	MSTVROT431440	MSTVROT431450	MSTVROT431460
MSTVROT431520	MSTVROT431625	MSTVROT431630	MSTVROT431635	MSTVROT431640
MSTVROT621415	MSTVROT621425	MSTVROT621430	MSTVROT621435	MSTVROT621440
MSTVROT621450	MSTVROT621460	MSTVROT621520	MSTVROT621525	MSTVROT621625
MSTVROT621630	MSTVROT621635	MSTVROT621640	MSTVROT625415	MSTVROT625425
MSTVROT625430	MSTVROT625435	MSTVROT625440	MSTVROT625450	MSTVROT625460
MSTVROT625520	MSTVROT625625	MSTVROT625630	MSTVROT625635	MSTVROT625640
MSTVROT631415	MSTVROT631425	MSTVROT631430	MSTVROT631435	MSTVROT631440
MSTVROT631450	MSTVROT631460	MSTVROT631520	MSTVROT631625	MSTVROT631630
MSTVROT631635	MSTVROT631640	MDDVROT325AST	MSTVROT425ATK	