

DECLARATION OF CONFORMITY

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

Sterile root canal instruments for repeated use

PRODUCT NAME / MD NOMENCLATURE

Produktbezeichnung / MP Nomenklatur

Product Name	GMDN	UMDN
C-Pilot files	31878	16-662
Finger Plugger	41876	16-662
Finger Spreader	37678	16-662
Flexicut files	31878	16-662
Hedstroem files	31878	16-662
K-reamers	31878	16-662
K-files	31878	16-662
NiTi Finger Spreader	37678	16-662
NiTi K-files	31878	16-662
Stainless hand files for RECIPROC	31878	16-662
Hand files for VDW.ROTATE	31878	16-662

RISK CLASS

Risikoklasse

Class Is / Rule 6

**CATALOG (SKU) NUMBER OR BASIC
UDI-DI**

Artikelnummer oder Basic UDI-DI

Please refer to PRODUCT LIST - ATTACHMENT

COMMON SPECIFICATION

Spezifikation

The technical documentation is available as paper version
on file.**NOTIFIED BODY NAME**

Name der Benannten Stelle

TÜV SÜD Product Service GmbH

Ridlerstr. 65
80339 München / Munich
CE 0123**NOTIFIED BODY IDENTIFICATION
NUMBER**

Identifikation der Benannten Stelle

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KONFORMITÄTSERKLÄRUNG

APPLICABLE EU LEGISLATIONS & CONFORMITY ASSESSMENT PROCEDURE

Konformitätsbewertungsverfahren

CERTIFICATE(S) ISSUED,
Ausstellung des Zertifikats

CERTIFICATE(S) VALIDITY DATE
Gültigkeitsdatum des Zertifikats

☒ **MDD 93/42/EWG, Amendment 2007/47/EEC.**
Annex V

☐ **MDR 2017/745**

Certificate No / Rev.: G2S 015409 0027 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

VALIDITY DATE

Please see: CERTIFICATE(S) VALIDITY DATE

REV. Nr.

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

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

C-Pilot files

V040368019006	V040368019008	V040368019010	V040368019012	V040368019015
V040368019210	V040368021006	V040368021008	V040368021010	V040368021012
V040368021015	V040368021210	V040368025006	V040368025008	V040368025010
V040368025012	V040368025015	V040368025210		

Finger Plugger

V040399025015	V040399025020	V040399025025	V040399025030	V040399025035
V040399025040	V040399025230			

Finger Spreader

V040395025015	V040395025020	V040395025025	V040395025030	V040395025035
V040395025040	V040395025230			

Flexicut files

V040364021015	V040364021020	V040364021025	V040364021030	V040364021035
V040364021040	V040364021230	V040364025015	V040364025020	V040364025025
V040364025030	V040364025035	V040364025040	V040364025230	

Hedstroem files

V040373021008	V040373021010	V040373021015	V040373021020	V040373021025
V040373021030	V040373021035	V040373021040	V040373021045	V040373021050
V040373021055	V040373021060	V040373021070	V040373021080	V040373021090
V040373021100	V040373021110	V040373021220	V040373021230	V040373021240
V040373021250	V040373025008	V040373025010	V040373025015	V040373025020
V040373025025	V040373025030	V040373025035	V040373025040	V040373025045
V040373025050	V040373025055	V040373025060	V040373025070	V040373025080
V040373025090	V040373025100	V040373025110	V040373025120	V040373025130
V040373025140	V040373025220	V040373025230	V040373025240	V040373025260
V040373028008	V040373028010	V040373028220	V040373031008	V040373031010
V040373031015	V040373031020	V040373031025	V040373031030	V040373031035
V040373031040	V040373031045	V040373031050	V040373031055	V040373031060
V040373031070	V040373031080	V040373031090	V040373031100	V040373031110
V040373031120	V040373031130	V040373031140	V040373031220	V040373031230
V040373031240	V040373031260			

K-reamers

V040353021006	V040353021008	V040353021010	V040353021015	V040353021020
V040353021025	V040353021030	V040353021035	V040353021040	V040353021045
V040353021050	V040353021055	V040353021060	V040353021070	V040353021080
V040353021090	V040353021100	V040353021110	V040353021210	V040353021230
V040353021240	V040353021250	V040353025006	V040353025008	V040353025010
V040353025015	V040353025020	V040353025025	V040353025030	V040353025035
V040353025040	V040353025045	V040353025050	V040353025055	V040353025060
V040353025070	V040353025080	V040353025090	V040353025100	V040353025110
V040353025120	V040353025130	V040353025140	V040353025210	V040353025230
V040353025240	V040353025260	V040353028006	V040353028008	V040353028010
V040353028210	V040353031006	V040353031008	V040353031010	V040353031015

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V040353031020	V040353031025	V040353031030	V040353031035	V040353031040
V040353031045	V040353031050	V040353031055	V040353031060	V040353031070
V040353031080	V040353031090	V040353031100	V040353031110	V040353031120
V040353031130	V040353031140	V040353031210	V040353031230	V040353031240
V040353031260				

K-files

V040363021006	V040363021008	V040363021010	V040363021012	V040363021015
V040363021017	V040363021020	V040363021025	V040363021030	V040363021035
V040363021040	V040363021045	V040363021050	V040363021055	V040363021060
V040363021070	V040363021080	V040363021090	V040363021100	V040363021110
V040363021210	V040363021230	V040363021240	V040363021250	V040363025006
V040363025008	V040363025010	V040363025012	V040363025015	V040363025017
V040363025020	V040363025025	V040363025030	V040363025035	V040363025040
V040363025045	V040363025050	V040363025055	V040363025060	V040363025070
V040363025080	V040363025090	V040363025100	V040363025110	V040363025120
V040363025130	V040363025140	V040363025210	V040363025230	V040363025240
V040363025260	V040363028006	V040363028008	V040363028010	V040363028210
V040363031006	V040363031008	V040363031010	V040363031015	V040363031020
V040363031025	V040363031030	V040363031035	V040363031040	V040363031045
V040363031050	V040363031055	V040363031060	V040363031070	V040363031080
V040363031090	V040363031100	V040363031110	V040363031120	V040363031130
V040363031140	V040363031210	V040363031230	V040363031240	V040363031260

NiTi Finger Spreader

V040392025015	V040392025020	V040392025025	V040392025030	V040392025035
V040392025040	V040392025230			

NiTi K-files

V040362021015	V040362021020	V040362021025	V040362021030	V040362021035
V040362021040	V040362021045	V040362021050	V040362021055	V040362021060
V040362021230	V040362025015	V040362025020	V040362025025	V040362025030
V040362025035	V040362025040	V040362025045	V040362025050	V040362025055
V040362025060	V040362025230			

Stainless Files for RECIPROC

V040009025321

Hand files for VDW.ROTATE

V040009025322