

DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

LEGAL MANUFACTURER
NAME, ADDRESS
 Name und Adresse des Herstellers

SINGLE REGISTRATION NUMBER (SRN)
 Registrierungsnummer des Herstellers

VDW GmbH
 Bayerwaldstraße 15
 81737 München / Munich
 Deutschland / Germany

DIMDI Registration Number: DE/0000029227

AUTHORIZED REPRESENTATIVE NAME, ADDRESS
 Name und Adresse des Repräsentanten

N/A

PRODUCT GROUP
 Produktgruppe

Root Canal Filling Points

PRODUCT NAME / MD NOMENCLATURE
 Produktbezeichnung / MP Nomenklatur

<i>Product Name</i>	<i>GMDN</i>	<i>UMDN</i>
Alpha Guttapercha	45081	17-611
Mtwo Guttapercha	45081	17-611
RECIPROC Gutta-percha	45081	17-611
RECIPROC <i>blue</i> Gutta-Percha	45081	17-611
VDW.ROTATE Gutta-Percha	45081	17-611
Guttafusion Obturators	45081	17-611
Guttafusion for RECIPROC Obturators	45081	17-611
Guttafusion for RECIPROC <i>blue</i> Obturators	45081	17-611
GuttaMaster Endodontic Obturators for Mtwo	45081	17-611
ISO standardized Guttapercha	45081	17-611
Conventional Guttapercha	45081	17-611
2Seal	36095	17-611
2Seal easymiX	36095	17-611

RISK CLASS
 Risikoklasse

Class IIa / Rule 8

CATALOG (SKU) NUMBER OR BASIC UDI-DI
 Artikelnummer oder Basic UDI-DI

Please refer to PRODUCT LIST - ATTACHMENT

COMMON SPECIFICATION
 Spezifikation

VDW.ROTATE and RECIPROC *blue* Gutta-percha:
 1000-TF_0_TDI_000054 (major version 0) : GPP
 (Hantech/JCM, VDW) Technical Documentation Index
 All other products: Technical documentation is available as paper version on file

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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

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KONFORMITÄTSERKLÄRUNG

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 (Date as automatic print date)

VALIDITY DATE

Please see: CERTIFICATE(S) VALIDITY DATE

REV. Nr.

34

 GmbH

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)

Alpha Guttapercha

V040521028015	V040521028020	V040521028025	V040521028030	V040521028035
V040521028040	V040521028230	V040522028015	V040522028020	V040522028025
V040522028030	V040522028035	V040522028040	V040522028230	

Mtwo Guttapercha

V040220028457	V040220428035	V040220428040	V040220428045	V040220428050
V040220428060	V040220528030	V040220628025	V040220628030	V040220628035
V040220628040	V040220728025			

RECIPROC Gutta-percha

V040214028025	V040214028040	V040214028050	V040214028237	
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RECIPROC blue Gutta-Percha

V040258028025	V040258028040	V040258028050	V040258028237	
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VDW.ROTATE Gutta-Percha

M00VRGPF00425	M00VRGPF00430	M00VRGPF00435	M00VRGPF00440	M00VRGPF00450
M00VRGPF00625	M00VRGPF00630	M00VRGPF00635	M00VRGPF00640	M00VRGPF00AST

ISO standardized Guttapercha (V01 - ANTAEOS, V02 - Beutelrock, V03 - Zipperer)

V010525028015	V010525028020	V010525028025	V010525028030	V010525028035
V010525028040	V010525028045	V010525028050	V010525028055	V010525028060
V010525028070	V010525028080	V010525028230	V010525028240	V010525028260
V010528028015	V010528028020	V010528028025	V010528028030	V010528028035
V010528028040	V010528028230	V010529028015	V010529028020	V010529028025
V010529028030	V010529028035	V010529028040	V010529028230	
V020525028015	V020525028020	V020525028025	V020525028030	V020525028035
V020525028040	V020525028045	V020525028050	V020525028055	V020525028060
V020525028070	V020525028080	V020525028230	V020525028240	V020525028260
V020528028015	V020528028020	V020528028025	V020528028030	V020528028035
V020528028040	V020528028230	V020529028015	V020529028020	V020529028025
V020529028030	V020529028035	V020529028040	V020529028230	
V030525028015	V030525028020	V030525028025	V030525028030	V030525028035
V030525028040	V030525028045	V030525028050	V030525028055	V030525028060
V030525028070	V030525028080	V030525028230	V030525028240	V030525028260
V030528028015	V030528028020	V030528028025	V030528028030	V030528028035
V030528028040	V030528028230	V030529028015	V030529028020	V030529028025
V030529028030	V030529028035	V030529028040	V030529028230	

Conventional Guttapercha (V01 - ANTAEOS, V02 - Beutelrock, V03 - Zipperer)

V010542020431	V010542020441	V010542020451	V010542020461	V010542020471
V010542020477				
V020542020431	V020542020441	V020542020451	V020542020461	V020542020471
V020542020477				
V030542020431	V030542020441	V030542020451	V030542020461	V030542020471
V030542020477				

GuttaMaster Endodontic Obturators for Mtwo

V040505025020	V040505025025	V040505025030	V040505025035	V040505025040
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V040505025045	V040505025050	V040505025060	V040506025020	V040506025025
V040506025030	V040506025035	V040506025040	V040506025045	V040506025520

Guttafusion Obturators

V040005000508	V041541000020	V041541000025	V041541000030	V041541000035
V041541000040	V041541000045	V041541000050	V041541000055	V041542000020
V041542000025	V041542000030	V041542000035	V041542000040	

Guttafusion for RECIPROC Obturators

V040005000507	V041531000025	V041531000040	V041531000050	V041532000025
V041532000040	V041532000050			

Guttafusion for RECIPROC *blue* Obturators

V041551000025	V041551000040	V041551000050	V041552000025	V041552000040
V041552000050				

2Seal

V041020

2Seal easymiX

V041025000001	V041025000002
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