

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

Device for root canal length determination
Software as accessory for endodontic equipment

PRODUCT NAME / MD NOMENCLATURE
Produktbezeichnung / MP Nomenklatur

**Raypex 6
VDW.Connect Locate**

<i>Product Name</i>	<i>GMDN</i>	<i>UMDN</i>
Raypex 6	16355	16-355
VDW.Connect Locate	16355	16-355
VDW.CONNECT App	60883	N/A
Lip clip	N/A	N/A
File Clip	N/A	N/A
Measuring Cable	N/A	N/A
Touch Probe	N/A	N/A
Charger	N/A	N/A
Battery	N/A	N/A

RISK CLASS
Risikoklasse

Apex Locators: Class IIa / Rule 10
Accessories:
- VDW.Connect App Class IIa

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

Please refer to PRODUCT LIST - ATTACHMENT

COMMON SPECIFICATION
Spezifikation

Raypex 6: Technical documentation is available as paper version on file

VDW.Connect Locate:
VDW.CONNECT Locate_Technical File Documents List:
1000-TF_0_TFDL_000020 (major version 13)
VDW.CONNECT App_Technical File Documents List:
1000-TF_0_TFDL_000051 (major version 7)

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KONFORMITÄTSERKLÄRUNG

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

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

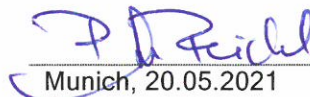
STELLUNGNAHME DER ERKLÄRUNG

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


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.

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

Product name	SKU
Raypex® 6	V041113000000
Raypex® 6 Accessories:	
Cable with plug	V041119000506
Charger	V041119000501
Battery	V041119000507
Raypex® 5 Accessories:	
Cable with plug	V040141000506
Charger	V040141000501
Battery	V040141000507
Accessories for Raypex® 5, Raypex® 6	
Lip clip	V040141000514
File Clip	V040141000515
Touch Probe	V040141000518
VDW.CONNECT Locate®	M00CLOC000000
VDW.CONNECT Locate® Accessories:	
VDW.CONNECT Locate Measurement cable	M00CLOC1ACCBL
VDW.CONNECT Locate File Clip	M00CLOC2ACFCL
VDW.CONNECT Locate Lip Clip	M00CLOC5ACLCL
VDW.CONNECT Locate Rechargeable Battery	M00CLOC2ACBAT
VDW.CONNECT Locate Charger	M00CLOC1ACCHG
VDW.CONNECT Drive Measurement Cable	M00CLOC1ACHPA