

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 Version 2.1.0	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
Disposable Polyethylene Barrier Sleeve - apex locator	61049	N/A
Disposable Polyethylene Barrier Sleeve - iPad mini 4	61049	N/A
Disposable Polyethylene Barrier Sleeve - iPad	61049	N/A
Disposable Polyethylene Barrier Sleeve - iPad Pro 10.5	61049	N/A
Disposable Polyethylene Barrier Sleeve - iPad Pro 12.9	61049	N/A
iPad Stand	N/A	N/A

RISK CLASS
Risikoklasse

Apex Locators: Class IIa / Rule 10
Accessories:
- VDW.Connect App Class IIa
- Sleeves and iPad stand Class I / Rule 1

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

Please refer to PRODUCT LIST - ATTACHMENT

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KONFORMITÄTSERKLÄRUNG

COMMON SPECIFICATION

Spezifikation

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

VDW.Connect Locate: 1000-TF_0_TFDL_000020 [6] :
VDW.CONNECT Locate_Technical File Documents List
1000-TF_0_TFDL_000051 [2] : VDW.CONNECT
App_Technical File Documents List**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

DECLARATION OF CONFORMITY 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, 07.08.2019

VALIDITY DATE

Please see: CERTIFICATE(S) VALIDITY DATE

REV. Nr.

07

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

DECLARATION OF CONFORMITY

KONFORMITÄT SERKLÄRUNG

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

Product name	SKU
Raypex 6	V041113000000
Raypex 6 accessories:	
Lip clip	V040141000514
File Clip	V040141000515
Measuring Cable	V040141000516
Touch Probe	V040141000518
Charger	V041119000501
Cable with plug	V041119000506
Battery	V041119000507
Raypex 5 accessories:	
Measuring Cable	V040141000506
Charger	V040141000501
Battery	V040141000507
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
Rechargeable Battery for VDW.CONNECT Locate	M00CLOC2ACBAT
Charger for VDW.CONNECT Locate	M00CLOC1ACCHG
VDW.CONNECT Drive Measurement Cable	M00CLOC1ACHPA
VDW.CONNECT Locate Disposable Polyethylene Barrier Sleeve	M00CLOC1ACBAR
VDW.CONNECT iPad Stand	M00CO00STA000
VDW.CONNECT Disposable Polyethylene Barrier Sleeve-iPad mini 4	M00CO00079BAR
VDW.CONNECT Disposable Polyethylene Barrier Sleeve-iPad	M00CO00097BAR
VDW.CONNECT Disposable Polyethylene Barrier Sleeve-iPad Pro 10.5	M00CO00105BAR
VDW.CONNECT Disposable Polyethylene Barrier Sleeve-iPad Pro 12.9	M00CO00129BAR