

We / Wir

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1

78567 Fridingen

Germany

SRN: DE-MF-000005515

hereby declare under our sole responsibility as manufacturer that the following medical devices	<i>erklären in alleiniger Verantwortung als Hersteller, dass die folgenden Medizinprodukte</i>
---	--

of the product group	<i>der Produktgruppe</i>
Trocar spikes and obturators, reusable, TD-110	

Device name	<i>Name des Medizinprodukts</i>
See the attached device list.	<i>Siehe angehängte Artikelliste.</i>


EMDN	<i>EMDN</i>
L0312 SURGICAL TROCAR, REUSABLE	

UMDNS No.	UMDNS Name English	UMDNS Name German
14-154	Trocars	Trokar
16-155	Obturators, Endoscopic	Verschlussinstrument, endoskopisch

Risk Class MDR	<i>Risikoklasse MDR</i>
See the attached device list.	<i>Siehe angehängte Artikelliste.</i>

Basic UDI-DI	<i>Basis UDI-DI</i>
4049356TD-110GW	

Declaration of Conformity (DoC)
Konformitätserklärung

in accordance with	gemäß
Article 120 of the Regulation (EU) 2017/745 on Medical Devices (MDR) in the version according to Regulation (EU) 2023/607	Artikel 120 der Verordnung (EU) 2017/745 über Medizinprodukte (MDR) in der Fassung nach Verordnung (EU) 2023/607
are in conformity with the following requirements:	mit den folgenden Anforderungen übereinstimmen:
Council Directive 93/42/EEC (MDD) of 14 June 1993 concerning medical devices	Richtlinie 93/42/EWG (MDD) des Rates vom 14. Juni 1993 über Medizinprodukte
Notified Body: DQS Identification No: 0297 DQS Medizinprodukte GmbH August-Schanz-Strasse 21 60433 Frankfurt am Main Germany	Benannte Stelle: DQS Kennnummer: 0297 DQS Medizinprodukte GmbH August-Schanz-Strasse 21 60433 Frankfurt am Main Germany
valid until Gültig bis	2028-12-31
Reference to the previous DoC Referenz zur vorherigen DoC	MDD DoC, expiration 2024-05-26
Signed by Person Responsible for Regulatory Compliance (PRRC) (MDR Article 15):	Unterzeichnet von der für die Einhaltung der Regulierungsvorschriften verantwortlichen Person (MDR-Artikel 15):
Name Name	Ayfer Bektas
Role Rolle	Person Responsible for Regulatory Compliance (PRRC)
Signature Unterschrift	 RUDOLF RUDOLF Medical GmbH + Co. KG 78567 Fridingen, Germany Tel. +49 7463 9956-0 sales@rudolf-med.com www.rudolf-med.com
Date of issue Datum der Ausstellung	2024-11-28
Place of issue Ort der Ausstellung	Fridingen, Germany

Annex: Translations

Übersetzungen

Translation of the following text:

Übersetzung des folgenden Textes:

- We hereby declare under our sole responsibility as manufacturer that the following medical devices in accordance with [...] are in conformity with the following requirements:
- See the attached device list.
- valid until:
- Reference to the previous DoC

Language / Sprache	Translation / Übersetzung
French	Nous déclarons par la présente, sous notre seule responsabilité de fabricant, que les dispositifs médicaux suivants, conformément à [...], sont conformes aux exigences suivantes : Voir la liste des dispositifs médicaux ci-jointe. Valable jusqu'à Référence à la déclaration de conformité précédente
Italian	Con la presente dichiariamo, sotto la nostra propria responsabilità come fabbricante, che i seguenti dispositivi medici in accordo con [...] sono conformi ai seguenti requisiti: Vedi l'elenco dei dispositivi medici allegato. valido fino al Riferimento alla precedente dichiarazione di conformità
Spanish	Por la presente declaramos, bajo nuestra exclusiva responsabilidad como fabricante, que los siguientes productos sanitarios de conformidad [...] son conformes con los siguientes requisitos: Véase la lista de productos sanitarios adjunta. Válido hasta el Referencia a la anterior declaración de conformidad

Attachment: Device List

Anhang: Artikelliste

REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
AT040-021	TROCAR FOR ARHTROSCOPE SHEATHSØ 5,5 MM, Ø 6,0 MM, Ø 6,5 MM	404935628542	6	lr	TD-110
AT040-022	TROCAR FOR ARTHROSCOPE SHEATHSØ 5,5 MM, Ø 6,0 MM, Ø 6,5 MM,	404935628543	6	lr	TD-110
AT040-023	TROCAR FOR ARHTROSCOPE SHEATHSØ 5,5 MM, Ø 6,0 MM, Ø 6,5 MM	404935628544	6	lr	TD-110
AT040-121	TROCAR FOR ARHTROSCOPE SHEATHS Ø 5.5 MM,ATRAUMATIC, TRIANGULAR SHARP,	404935628553	6	lr	TD-110
AT040-122	TROCAR FOR ARHTROSCOPE SHEATHS Ø 5.5 MM,ATRAUMATIC, CONICAL BLUNT,	404935628554	6	lr	TD-110
AT045-011	TROCARFOR INFLOW IRRIGATION CANNULA Ø4.5MM	404935646398	6	lr	TD-110
AT045-012	OBTURATORFOR INFLOW IRRIGATION CANNULA Ø4.5MM	404935646399	6	lr	TD-110
AT045-021	TROCAR SPIKE, FOR CANNULA Ø 3.2 MM,WITH LUER-LOCK	404935629320	6	lr	TD-110
AT045-022	OBTURATOR, FOR CANNULA Ø 3.2 MM,WITH LUER-LOCK	404935629321	6	lr	TD-110
AT045-032	TROCAR SPIKE, FOR CANNULA Ø 4.5 MM,WITH LUER-LOCK	404935629325	6	lr	TD-110
AT045-033	OBTURATOR, FOR CANNULA Ø 4.5 MM,WITH LUER-LOCK	404935629326	6	lr	TD-110
CY040-486	STANDARD OBTURATOR RCS,FOR LITHOTRIPSY SHEATH 24 FR.,RUDOLF CLICK SYSTEM (RCS)	404935628195	6	lr	TD-110
CY070-121	STANDARD OBTURATOR FOR 7,5 FR.CYSTO-URETHROSCOPE SHEATH	404935628808	6	lr	TD-110
CY095-121	STANDARD OBTURATOR FOR 9,5 CHARR.CYSTO-URETHROSCOPE SHEATH	404935611560	6	lr	TD-110
CY110-121	STANDARD OBTURATOR FOR 11 CHARR.CYSTO-URETHROSCOPE SHEATH	404935611561	6	lr	TD-110
CY130-121	STANDARD OBTURATOR FOR 13 CHARR.CYSTO-URETHROSCOPE SHEATH	404935611562	6	lr	TD-110
CY150-122	STANDARD OBTURATOR RCS,FOR CYSTO-URETHROSCOPE SHEATH 15FR.,RUDOLF CLICK SYSTEM (RCS)	404935628580	6	lr	TD-110
CY170-121	STANDARD OBTURATOR17 FR.	404935611564	6	lr	TD-110

REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
CY170-122	STANDARD OBTURATOR RCS, FOR CYSTO-URETHROSCOPE SHEATH 17FR., RUDOLF CLICK SYSTEM (RCS)	404935628600	6	lr	TD-110
CY190-121	STANDARD OBTURATOR 19 FR.	404935611566	6	lr	TD-110
CY190-122	STANDARD OBTURATOR RCS, FOR CYSTO-URETHROSCOPE SHEATH 19FR., RUDOLF CLICK SYSTEM (RCS)	404935628601	6	lr	TD-110
CY190-131	VIEWING OBTURATOR 19 FR.	404935611567	6	lr	TD-110
CY210-121	STANDARD OBTURATOR 21 FR.	404935611568	6	lr	TD-110
CY210-122	STANDARD OBTURATOR RCS, FOR CYSTO-URETHROSCOPE SHEATH 21FR., RUDOLF CLICK SYSTEM (RCS)	404935628602	6	lr	TD-110
CY230-121	STANDARD OBTURATOR 23 FR.	404935611570	6	lr	TD-110
CY230-122	STANDARD OBTURATOR RCS, FOR CYSTO-URETHROSCOPE SHEATH 23FR., RUDOLF CLICK SYSTEM (RCS)	404935628185	6	lr	TD-110
CY230-131	VIEWING OBTURATOR 23 FR. FOR SHEATH CY230-101	404935611571	6	lr	TD-110
CY230-141	VIEWING OBTURATOR RCS, 23 FR., FOR LASER CYSTO-URETHROSCOPE SHEATH, RUDOLF CLICK SYSTEM (RCS)	404935628819	6	lr	TD-110
CY230-143	STANDARD OBTURATOR RCS, 23 FR. FOR LASER CYSTO-URETHROSCOPE SHEATH, RUDOLF CLICK SYSTEM (RCS)	404935628820	6	lr	TD-110
CY250-121	STANDARD OBTURATOR 25 FR.	404935611572	6	lr	TD-110
CY250-122	STANDARD OBTURATOR RCS, FOR CYSTO-URETHROSCOPE SHEATH 25FR., RUDOLF CLICK SYSTEM (RCS)	404935628603	6	lr	TD-110
HY020-121	STANDARD OBTURATOR	404935611574	6	lr	TD-110
HY020-231	STANDARD OBTURATOR	404935611575	6	lr	TD-110
HY029-121	STANDARD OBTURATOR	404935611576	6	lr	TD-110
HY029-231	STANDARD OBTURATOR	404935611577	6	lr	TD-110
HY029-232	OBTURATOR FOR HYSTEROSCOPE SHEATH, 5MM	404935628190	6	lr	TD-110
HY040-121	STANDARD OBTURATOR	404935611578	6	lr	TD-110
HY040-231	STANDARD OBTURATOR	404935611579	6	lr	TD-110
HY040-351	STANDARD OBTURATOR	404935611580	6	lr	TD-110
HY040-381	STANDARD OBTURATOR	404935611581	6	lr	TD-110

REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
RC170-122	STANDARD OBTURATOR 17,5/18,5 CH,CLICK SYSTEM, GRÜN	404935630749	6	lr	TD-110
RC190-121	STANDARD OBTURATOR 19/22 CH, CLICKSYSTEM, WHITE	404935611585	6	lr	TD-110
RC190-122	STANDARD OBTURATOR 19/22 CH, BAYONETSYSTEM, TURQUOISE	404935630723	6	lr	TD-110
RC190-131	VIEWING OBTURATOR FORRESECTOSCOPE SHEATH 19FR./CHARR.	404935611586	6	lr	TD-110
RC240-121	STANDARD OBTURATOR 24/26 CH, BAJONETTSYSTEM, YELLOW	404935611587	6	lr	TD-110
RC240-122	STANDARD OBTURATOR 24/26 CH, CLICKSYSTEM, PURPLE	404935630713	6	lr	TD-110
RC240-131	VIEWING OBTURATOR FORRESECTOSCOPES 26FR./CHARR.	404935611588	6	lr	TD-110
RC240-132	VIEWING OBTURATOR 24/26 CLICK SYSTEMPURPLE	404935630719	6	lr	TD-110
RC240-141	DEFLECTING OBTURATOR24 FR./CHARR.	404935611589	6	lr	TD-110
RC240-151	VIEWING OBTURATOR WITH 5FR./CHARR.INSTRUMENT CHANNEL FORRESECTOSCOPE 26FR./CHARR.	404935611590	6	lr	TD-110
RC300-301	TROCAR WITH PYRAMIDAL TIP	404935602375	6	lr	TD-110
RC300-302	TROCAR WITH CANNULA TIP	404935602376	6	lr	TD-110
RUT210-121	STANDARD OBTURATOR21 FR.		6	lr	TD-110
TR300-055	TROCAR,CONICAL POINTØ 5.5 MM	404935602274	6	lr	TD-110
TR300-110	TROCAR,CONICAL POINTFOR TROKARSLEEVE WITH CANNULATION Ø 10MM	404935602277	6	lr	TD-110
TR300-125	TROCAR,CONICAL POINTØ 12.5 MM	404935602278	6	lr	TD-110
TR310-054	TROCAR, WITH TRIANGULAR POINTØ 5.5 MM	404935602284	6	lr	TD-110
TR310-055	TROCAR, WITH TRIANGULAR POINTØ 5.5 MM	404935602285	6	lr	TD-110
TR310-110	TROCAR, WITH TRIANGULAR POINTFOR TROKARSLEEVE WITH CANNULATION Ø 10MM	404935602290	6	lr	TD-110
TR310-125	TROCAR,WITH TRIANGULAR POINTØ 12.5 MM	404935602291	6	lr	TD-110
TR330-055	TROCAR FOR HASSON, CONICAL BLUNTØ 5.5 MM	404935602304	6	lr	TD-110
TR330-110	TROCAR FÜR HASSON, CONICAL BLUNTFOR TROKARSLEEVE WITH CANNULATION Ø 10MM	404935602306	6	lr	TD-110

TD-110 - trocar spikes and obturators

REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
TR330-125	TROCAR FÜR HASSON, CONICAL BLUNTØ 12,5 MM	404935602307	6	lr	TD-110
TR350-055	SECURITY TROCAR SPIKE,Ø 5.5 MM	404935604542	6	lr	TD-110
TR350-110	SECURITY TROCAR SPIKE,Ø 11 MM	404935604544	6	lr	TD-110
TR350-125	SECURITY TROCAR SPIKE,Ø 12.5 MM	404935604545	6	lr	TD-110
UT210-116	VIEWING OBTURATOR FOR URETHROTOME	404935627764	6	lr	TD-110
UT210-121	STANDARD OBTURATOR21 FR.	404935627765	6	lr	TD-110
UT210-131	OBTURATOR 21 FR.1X5 FR. INSTRUMENT CHANNEL	404935627766	6	lr	TD-110