

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>
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of the product group	<i>der Produktgruppe</i>
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Elevators, reusable, TD-095

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

Siehe angehängte Artikelliste.

EMDN	<i>EMDN</i>
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L0902 ORTHOPAEDIC SURGERY LEVERS, REUSABLE

UMDNS No.	UMDNS Name English	UMDNS Name German
11-266	Dilator, uterine	Dilatator, uterus
11-504	Elevators	Elevatorium
12-028	Hooks	Haken
13-707	Spreaders	Spreizer
15-741	Rasps, Bone	Raspel, Knochen



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

Siehe angehängte Artikelliste.

Basic UDI-DI	<i>Basis UDI-DI</i>
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4049356TD-095HT

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 2023-11-20
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	 
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
HY500-010	UTERUS MANIPULATOR BY COHEN, ONLY	404935617870	6	lr	TD-095
HY500-020	PORTIO ADAPTER SMALL	404935609232	6	lr	TD-095
HY500-030	PORTIO ADAPTER LARGE	404935609233	6	lr	TD-095
HY500-110	UTERUSMANIPULATOR ONLY	404935601850	6	lr	TD-095
HY500-120	UTERUS OBTURATOR, THICK, EXTRA LONGWL 10x100 MM	404935601845	6	lr	TD-095
HY500-121	UTERUS OBTURATOR, MEDIUM, LONGWL 8x80 MM	404935601846	6	lr	TD-095
HY500-122	UTERUS OBTURATOR, THIN, LONGWL 3x55 MM	404935601847	6	lr	TD-095
HY500-123	UTERUS OBTURATOR, THIN, SHORTWL 3x45 MM	404935601848	6	lr	TD-095
HY500-124	CONICAL ADAPTER, LARGE THORNWL 3,3x70 MM	404935616814	6	lr	TD-095
HY500-125	CONICAL ADAPTOR, SHORT THORNWL 3,3x60 MM	404935616815	6	lr	TD-095
LP323-000	HANDLE, ONLYFOR LP323-015 + RS005-000FOR LP323-020 + RS009-000	404935615732	6	lr	TD-095
LP323-002	HANDLE, ONLY FOR LP 323-040	404935627113	6	lr	TD-095
LP323-005	LIVER ELEVATORS, DETACHABLE, COMPLETEW. HANDLE, TUBE A. INSERTWL 355 MM, Ø 5 MM	404935615733	6	lr	TD-095
LP323-015	INSERT, ONLYWL 355 MM, Ø 5 MM	404935615735	6	lr	TD-095
LP323-020	INSERT, ONLYWL 390 MM, Ø 10 MM	404935615736	6	lr	TD-095
LP323-040	INSERT, ONLYWL 330 MM, Ø 10 MM	404935627117	6	lr	TD-095
RU 4616-01	SAGITTAL SPLIT SEPARATOR SMITH, RIGHT18,5CM/7 1/4", 9 MM	404935629172	6	lr	TD-095
RU 4616-02	SAGITTAL SPLIT SEPARATOR SMITH, LEFT18,5CM/7 1/4", 9 MM	404935629173	6	lr	TD-095
RU 5418-12	ELEVATOR, CUSHING21,5 CM - 8 1/2", 6 MM	404935621342	6	lr	TD-095
RU 5420-20	LANGENBECK ELEVATOR, 8MM, 20CM	404935621324	6	lr	TD-095
RU 5421-20	LANGENBECK ELEVATOR, 10MM, 20CM	404935621325	6	lr	TD-095
RU 5423-15	MASS.GEN.HOSP. ELEVATOR, 15 CM	404935621363	6	lr	TD-095
RU 5425-17	ELEVATOR, WILLIGER17 CM - 6 3/4", 5,5 MM	404935621320	6	lr	TD-095
RU 5426-16	ELEVATOR, WILLIGER16 CM - 6 1/4", 4 MM	404935621321	6	lr	TD-095
RU 5427-20	PERIOSTEAL ELEVATOR QUERVAIN, CURVED, BLUNT, 6 MM, 19.5 CM - 7 3/4"	404935621323	6	lr	TD-095

REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
RU 5428-16	ELEVATOR, 16 CM - 6 1/4", 5,5 MM	404935621338	6	lr	TD-095
RU 5431-01	PERIOSTEAL ELEVATOR KÖNIG,CURVED,BLUNT,4.5 MM, 15.5 CM - 6"	404935621327	6	lr	TD-095
RU 5432-21	ALDERDYCE ELEVATOR, 21 CM	404935621368	6	lr	TD-095
RU 5434-19	ELEVATOR, MC DONALD, BLUNT18,5 CM, 6 MM	404935621367	6	lr	TD-095
RU 5435-17	WATSON-CHEYNE ELEVATOR, 17,5CM	404935621365	6	lr	TD-095
RU 5437-14	BONE LEVER, 2,8 MM, 14 CM	404935617105	6	lr	TD-095
RU 5438-15	BONE LEVER, 5,0 MM, 15 CM	404935617080	6	lr	TD-095
RU 5438-55	BONE LEVER, 7,0 MM, 15 CM	404935617101	6	lr	TD-095
RU 5439-01	BUCK-GRAMCKO LEVER, 15 CM	404935617095	6	lr	TD-095
RU 5439-02/12	BONE LEVER, 2MM/15MM, (L) 12,5 CM	404935608159	6	lr	TD-095
RU 5440-06	MINI-HOHMANN LEVER, 6 MM,16 CM	404935617085	6	lr	TD-095
RU 5440-08	MINI-HOHMANN LEVER, 8 MM,16 CM	404935617086	6	lr	TD-095
RU 5440-24	BONE LEVER, 24 MM, 26,5 CM	404935617103	6	lr	TD-095
RU 5441-24	LANGE-HOHMANN LEVER,22 MM,26CM	404935615920	6	lr	TD-095
RU 5442-10	HOHMANN LEVER, 8 MM, 22 CM	404935617090	6	lr	TD-095
RU 5442-17	HOHMANN LEVER,17 MM, 24 CM	404935617091	6	lr	TD-095
RU 5442-18	HOHMANN LEVER,17 MM, 24 CM	404935617092	6	lr	TD-095
RU 5442-24	HOHMANN LEVER,22 MM, 26 CM	404935617093	6	lr	TD-095
RU 5442-34	HOHMANN LEVER, 33MM, 28,5CM	404935617174	6	lr	TD-095
RU 5442-42	HOHMANN LEVER,43 MM, 24 CM	404935617094	6	lr	TD-095
RU 5442-50	HOHMANN LEVER,43 MM,24,5CM	404935617089	6	lr	TD-095
RU 5442-65	HOHMANN LEVER,70 MM, 24 CM	404935617175	6	lr	TD-095
RU 5443-01/22	WAGNER BONE LEVER, 22 CM	404935617081	6	lr	TD-095
RU 5444-01	HOHMANN-ALDINGER LEV. 27CM, 24MM	404935618113	6	lr	TD-095
RU 5444-06	VERBRUGGE-MÜLLER LEV.42MM,24CM	404935617168	6	lr	TD-095
RU 5444-06/65	VERBRUGGE-MÜLLER LEV.65MM,24,5	404935617169	6	lr	TD-095

REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
RU 5444-10	LANE TRETOWAN LEVER, 21,5 CM	404935617088	6	lr	TD-095
RU 5444-11/25	LANE BONE LEVER, 25,5 CM	404935617087	6	lr	TD-095
RU 5444-12	BRISTOW BONE LEVER, 23 CM	404935617096	6	lr	TD-095
RU 5445-32	MURPHY-LANE BONE LEVER, 32 CM	404935617084	6	lr	TD-095
RU 5446-18	CHANDLER LEVER, 13 MM, 18 CM	404935617173	6	lr	TD-095
RU 5446-20	CHANDLER LEVER, 19 MM, 20 CM	404935617172	6	lr	TD-095
RU 5446-23	CHANDLER LEVER, 25 MM, 23 CM	404935617171	6	lr	TD-095
RU 5447-01	BLOUNT BONE LEVER, 26 CM	404935617097	6	lr	TD-095
RU 5447-02	BLOUNT BONE LEVER, 26 CM	404935617098	6	lr	TD-095
RU 5450-44	BENNETT BONE LEVER, 44MM, 24CM	404935617100	6	lr	TD-095
RU 5450-64	BENNETT BONE LEVER, 60MM, 24CM - 9 1/2"	404935617099	6	lr	TD-095
RU 6347-15	ELEVATOR FRAZIER, 15 CM - 6"	404935621770	6	lr	TD-095
RU 6348-01	ELEVATOR HOEN, ANGLED UPW., 15 CM - 6"	404935621767	6	lr	TD-095
RU 6348-02	ELEVATOR HOEN, STRONGLY ANGLED UPW.,15 CM - 6"	404935621768	6	lr	TD-095
RU 6352-03	DISSECTOR, SACHS, BLUNT21 CM - 8 1/4"	404935621769	6	lr	TD-095
RU 7908-32/01	ELEVATOR FOR LIFTING DRUM FORWARD,ANGLED 15°, 12 X 1 MM, 16 CM - 6 1/4"	404935603134	6	lr	TD-095
RU 8204-16	ELEVATOR HALLE, BLUNT18,5 CM - 7 1/4", 4 MM	404935608480	6	lr	TD-095
RU 8207-18	ELEVATOR, LEMPERT, SEMI-SHARP18,5 CM - 7 1/4"	404935621352	6	lr	TD-095
RU 8214-20	FREER SEPTUM ELEVATOR,US-MOD.,20CM	404935619595	6	lr	TD-095
RU 8215-20	HAJEK-BALLENGER SEPTUM-ELEVATOR,20CM,8"	404935628981	6	lr	TD-095
RU 8219-22	MCKENTY SEPTUM ELEVAT.22CM	404935604700	6	lr	TD-095
RU 8220-19	FREER SEPTUM-ELEVATOR, 18,5 CM, 7 1/4"	404935604709	6	lr	TD-095
RU 8231-16	ELEVATOR, 16,5 CM, 6 1/2", 4 MM	404935621353	6	lr	TD-095
RU 8232-18	FREER, ELEVATOR,16,5 CM/6 1/2"	404935621354	6	lr	TD-095
RU 8236-18	SEPTUM ELEVATOR, 18CM	404935604702	6	lr	TD-095
RU 8237-20	COTTLE ELEVATOR,GRAD.,20CM	404935622699	6	lr	TD-095
RU 8238-22	JOSEPH-COTTLE SEPTUM ELEV.22CM	404935610287	6	lr	TD-095
RU 8239-20	MASING SEPTUM ELEVATOR,20,5CM	404935610284	6	lr	TD-095

REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
RU 8239-22	MASING ELEVATOR, 22,5 CM, 8 3/4"	404935621355	6	lr	TD-095
RU 8240-16	JOSEPH PEROST ELEVATOR	404935610285	6	lr	TD-095
RU 8326-01	BOIES SEPTUM ELEVATOR 18 Cm	404935624096	6	lr	TD-095
RU 8326-02	GOLDMANN SEPTUM ELEVATOR 20 CM	404935619196	6	lr	TD-095
RU 8542-08	HURD TONSIL ELEVATOR,8MM, 22.5CM	404935602668	6	lr	TD-095
RU 8542-22	HURD TONSIL ELEVATOR,10MM, 22.5CM	404935602669	6	lr	TD-095
RU 8542-50	HURD ELEV., FENESTR.PAL.RETR.,11.5MM,9"	404935621332	6	lr	TD-095
RU 8543-60	SUCT.ELEV., 9"	404935606896	6	lr	TD-095
RU 8545-01	HENKE TONSIL ELEV.,COARSE,11.5MM, 9"	404935602650	6	lr	TD-095
RU 8545-02	HENKE TONSIL ELEVATOR,FINE,15MM, 9"	404935602651	6	lr	TD-095
RU 8836-07T	RHOTON ELEVATOR, TI,FIG.419 CM - 7 1/2",1,2 MM	404935608201	6	lr	TD-095
RU 8836-08T	RHOTON ELEVATOR, TI,FIG.519,0 CM - 7 1/2", 2,8 MM	404935608202	6	lr	TD-095