



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declarație de conformitate CE

RS009-000										
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000438944	INSTRUMENT CHIRURGICAL		TUB CU PIULIȚĂ ȘURUB DE FIXARE PENTRU SISTEMUL RUDOLF SCREW-IN, IZOLAT, Ø 10 MM, 330 MM	RS009-000	Germania	RUDOLF MEDICAL GMBH + CO. KG	LABROMED LABORATOR S.R.L	Rg04-000041	24-02-2023	

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RS000-948										
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000504888	INSTRUMENT ELECTROCHIR		PENSĂ CU CÂRLIG, Ø 10 MM 330 MM	RS000-948	Germania	RUDOLF MEDICAL GMBH + CO. KG	LABROMED LABORATOR S.R.L	Rg04- 000106	15-05-2023	

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Declaration of Conformity (DoC) Konformitätserklärung

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>
Endo instruments, reusable, TD-100	

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

EMDN	<i>EMDN</i>
L1204 LAPAROSCOPIC AND THORACOSCOPIC SURGERY FORCEPS REUSABLE	

UMDNS No.	UMDNS Name English	UMDNS Name German
11-775	Forceps, Biopsy	Zange, Biopsie
12-726	Needle Holders	Nadelhalter
13-630	Snares	Schlingeninstrument
15-221	Forceps, Other	Zange, sonstige
16-268	Forceps, Biopsy, Flexible Endoscopic	Zange, Biopsie, flexible Endoskopie
16-269	Forceps, Biopsy, Rigid Endoscopic	Zange, Biopsie, starre Endoskopie

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

Declaration of Conformity (DoC)
Konformitätserklärung

Basic UDI-DI	Basis UDI-DI
4049356TD-100GT	

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	 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

TD-100 - endo instruments

2024-10-18

REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
CY040-420	OPT. BIOPSY FCPS F.CYSTO-URETHROSCOPES0°/12°,DOUBLE ACTION	404935611251	6	Ir	TD-100
CY040-421	OPTICAL BIOPSY FORCEPS RCS,DOUBLE ACTION,RUDOLF CLICK SYSTEM (RCS)	404935628608	6	Ir	TD-100
CY040-430	OPT. BIOPSY FCPS F.CYSTO-URETHROSCOPES0°/12°,TROUGH CUTTING	404935611252	6	Ir	TD-100
CY040-431	OPTICAL BIOPSY FORCEPS RCS,THROUGH CUTTING,RUDOLF CLICK SYSTEM (RCS)	404935628610	6	Ir	TD-100
CY040-440	OPT. GRASPING FCPS F.CYSTO-URETHROSCOPES0°/12°,DOUBLE ACTION	404935611253	6	Ir	TD-100
CY040-460	OPT. BIOPSY FCPS F.CYSTO-URETHROSCOPES12°/30°,DOUBLE ACTION	404935611255	6	Ir	TD-100
CY040-481	OPTICAL STONE FORCEPSFOR RESECTOSCOPES 0°-30°	404935611257	6	Ir	TD-100
CY040-482	STONE FORCEPS RCS,FOR CYSTO-URETHROSCOPE (0°-30°)RUDOLF CLICK SYSTEM (RCS)	404935628193	6	Ir	TD-100
CY040-487	PUNCH WORKING ELEMENTFOR LITHOTRIPSYRUDOLF CLICK SYSTEM (RCS)	404935628219	6	Ir	TD-100
LP000-033	INSERT, TC NEEDLE HOLDER, 3-PART, STR.WL 330 MM, Ø 5MM	404935647695	6	Ir	TD-100
LP000-045	INSERT, TC NEEDLE HOLDER, 3-PART, STR.WL 450 MM, Ø 5MM	404935647696	6	Ir	TD-100
LP000-133	INSERT, TC NEEDLE HOLDER, 3-PART, LEFTWL 330 MM, Ø 5MM	404935647697	6	Ir	TD-100
LP000-145	INSERT, TC NEEDLE HOLDER, 3-PART, LEFTWL 450 MM, Ø 5MM	404935647698	6	Ir	TD-100
LP000-233	INSERT, TC NEEDLE HOLDER, 3-PART, RIGHTWL 330 MM, Ø 5MM	404935647699	6	Ir	TD-100
LP000-245	INSERT, TC NEEDLE HOLDER, 3-PART, RIGHTWL 450 MM, Ø 5MM	404935647700	6	Ir	TD-100

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REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
LP000-330	INSERT, NEEDLE HOLDER, 3-P., SELF-RIGHT.WL 330 MM, Ø 5MM	404935647701	6	Ir	TD-100
LP000-345	INSERT, NEEDLE HOLDER, 3-P., SELF-RIGHT.WL 450 MM, Ø 5MM	404935647702	6	Ir	TD-100
LP033-000	TUBE, WL 330 MM, Ø 5MM,FOR NEEDLE HOLDER 3-PART	404935647703	6	Ir	TD-100
LP045-000	TUBE, WL 450 MM, Ø 5MM,FOR NEEDLE HOLDER 3-PART	404935647704	6	Ir	TD-100
LP325-010	CHOLANGIOGRAM CLAMP, WITH RATCHETF.T.PLACEM. OF A CATH. WITH CHANNEL 7 FRWL 330 MM, Ø 5 MM	404935623643	6	Ir	TD-100
LP325-020	SPOON FORCEPS WITH IRRIGATION CHANNELWL 330 MM, Ø 10 MM	404935615425	6	Ir	TD-100
LP325-025	CLAW GRASPING FOCPS W IRRIGATION CHANNEL2X3 TEETH, WL 330 MM, Ø10 MM	404935616736	6	Ir	TD-100
LP352-021	NEEDLE HOLDER; TC; STRAIGHTWL 330MM; Ø5MM	404935646534	6	Ir	TD-100
LP352-022	NEEDLE HOLDER; TC; CURVED LEFTWL 330MM; Ø5MM	404935646533	6	Ir	TD-100
LP352-023	NEEDLE HOLDER; TC; CURVED RIGHTWL 330MM; Ø 5MM	404935646535	6	Ir	TD-100
LP353-033	NEEDLE HOLDER; TC; STRAIGHT; ERGOSTRAIGHT HANDLE; WL 330MM; Ø5MM	404935646544	6	Ir	TD-100
LP353-045	NEEDLE HOLDER; TC; STRAIGHT; ERGOSTRAIGHT HANDLE; WL 450MM; Ø5MM	404935646545	6	Ir	TD-100
LP353-133	NEEDLE HOLDER; TC; CURVED LEFT; ERGOSTRAIGHT HANDLE; WL 330MM; Ø5MM	404935646546	6	Ir	TD-100
LP353-145	NEEDLE HOLDER; TC; CURVED LEFT; ERGOSTRAIGHT HANDLE; WL 450MM; Ø5MM	404935646547	6	Ir	TD-100
LP353-233	NEEDLE HOLDER; TC; CURVED RIGHT; ERGOSTRAIGHT HANDLE; WL 330MM; Ø5MM	404935646548	6	Ir	TD-100
LP353-245	NEEDLE HOLDER; TC; CURVED RIGHT; ERGOSTRAIGHT HANDLE; WL 450MM; Ø5MM	404935646549	6	Ir	TD-100
LP353-330	NEEDLE HOLDER, TC, SELF-RIGHTING, ERGOSTRAIGHT HANDLE, WL 330MM, Ø 5MM	404935646550	6	Ir	TD-100

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REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
LP353-345	NEEDLE HOLDER, TC, SELF-RIGHTING, ERGOSTRAIGHT HANDLE, WL 450MM, Ø 5MM	404935646551	6	Ir	TD-100
LP354-033	NEEDLE HOLDER; TC; STRAIGHT; ERGOCURVED HANDLE; WL 330MM; Ø5MM	404935646536	6	Ir	TD-100
LP354-045	NEEDLE HOLDER; TC; STRAIGHT; ERGOCURVED HANDLE; WL 450MM; Ø5MM	404935646537	6	Ir	TD-100
LP354-133	NEEDLE HOLDER; TC; CURVED LEFT; ERGOCURVED HANDLE; WL 330MM; Ø5MM	404935646538	6	Ir	TD-100
LP354-145	NEEDLE HOLDER; TC; CURVED LEFT; ERGOCURVED HANDLE; WL 450MM; Ø5MM	404935646539	6	Ir	TD-100
LP354-233	NEEDLE HOLDER; TC; CURVED RIGHT; ERGOCURVED HANDLE; WL 330MM; Ø5MM	404935646540	6	Ir	TD-100
LP354-245	NEEDLE HOLDER; TC; CURVED RIGHT; ERGOCURVED HANDLE; WL 450MM; Ø5MM	404935646541	6	Ir	TD-100
LP354-330	NEEDLE HOLDER, TC, SELF-RIGHTING, ERGOCURVED HANDLE, WL 330MM, Ø 5MM	404935646542	6	Ir	TD-100
LP354-345	NEEDLE HOLDER, TC, SELF-RIGHTING, ERGO.CURVED HANDLE, WL 450MM, Ø 5MM	404935646543	6	Ir	TD-100
LP355-000	HANDLE, STRAIGHT, ERGONOMIC, FOR NEEDLE HOLDER 3-PART	404935647686	6	Ir	TD-100
LP356-000	HANDLE, CURVED, ERGONOMIC, FOR NEEDLE HOLDER 3-PART	404935647705	6	Ir	TD-100
LP357-000	HANDLE, STRAIGHT, HEAVY DESIGN, FOR NEEDLE HOLDER 3-PART	404935647711	6	Ir	TD-100
RF205-000	HANDLE ONLY FOR FLEXIBLE FORCEPS WITH DIAMETER 1.6MM AND LARGER	404935630799	6	Ir	TD-100
RF205-343	BIOP.-FORCEPS, SEMI-RIGID, OVAL, DOUBLE ACT 5 FR/1,6 MM, WL 340 MM	404935610134	6	Ir	TD-100
RF205-401	BIOP.-FORCEPS, FLEX., OVAL, DOUBLE ACTION 5 FR/1,6 MM, WL 400 MM	404935610187	6	Ir	TD-100

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REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
RF205-403	BIOP.-FORCEPS,SEMI-RIGID, OVAL5 FR/1,6 MM,WL 400 MMDDOUBLE ACTION	404935610135	6	Ir	TD-100
RF205-601	BIOP.-FORCEPS,FLEX.,OVAL,DOUBLE ACTION5 FR/1,6 MM,WL 600 MM	404935610188	6	Ir	TD-100
RF205-603	BIOP.-FORCEPS,SEMI-RIGID,OVAL,DOUBLE ACT5 FR/1,6 MM,WL 600 MM	404935610136	6	Ir	TD-100
RF207-343	BIOP.-FORCEPS,SEMI-RIGID,OVAL,DOUBLE ACT7 FR/2,3 MM,WL 340 MM	404935610140	6	Ir	TD-100
RF207-401	BIOP.-FORCEPS,FLEX.,OVAL,DOUBLE ACTION7 FR/2,3 MM,WL 400 MM	404935610193	6	Ir	TD-100
RF207-403	BIOP.-FORCEPS,SEMI-RIGID,OVAL,DOUBLE ACT7 FR/2,3 MM,WL 400 MM	404935610141	6	Ir	TD-100
RF209-343	BIOP.-FORCEPS,SEMI-RIGID,OVAL,DOUBLE ACT9 FR/3,0 MM,WL 340 MM	404935610143	6	Ir	TD-100
RF209-403	BIOP.-FORCEPS,SEMI-RIGID,OVAL,DOUBLE ACT9 FR/3,0 MM,WL 400 MM	404935610144	6	Ir	TD-100
RF215-341	SCISSORS,FLEX.,SINGLE ACTION5 FR/1,6 MM,WL 340 MM	404935605017	6	Ir	TD-100
RF215-343	SCISSORS,SEMI-RIGID,SINGLE ACTION5 FR/1,6 MM,WL 340 MM	404935604986	6	Ir	TD-100
RF215-343-1	SCISSORS INSERT ONLY,SEMI-RIGID,SINGLE ACTION,5 FR/1.6 MM,WL 340 MM TO RF215-343	404935629770	6	Ir	TD-100
RF215-401	SCISSORS,FLEX.,SINGLE ACTION5 FR/1,6 MM,WL 400 MM	404935605018	6	Ir	TD-100
RF215-403	SCISSORS,SEMI-RIGID,SINGLE ACTION5 FR/1,6 MM,WL 400 MM	404935604987	6	Ir	TD-100
RF215-601	SCISSORS,FLEX.,SINGLE ACTION5 FR/1,6 MM,WL 600 MM	404935605019	6	Ir	TD-100
RF217-343	SCISSORS,SEMI-RIGID,SINGLE ACTION7 FR/2,3 MM,WL 340 MM	404935604992	6	Ir	TD-100
RF227-343	HOOK SCISSORS,SEMI-RIGID,SINGLE ACTION7 FR/2,3 MM,WL 340 MM	404935618909	6	Ir	TD-100

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REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
RF245-343	BIOP.-FORCEPS,SEMI-RIGID,OVAL,SERR.5 FR/1,6 MM,WL 340 MM,DOUBLE ACTION	404935610146	6	Ir	TD-100
RF245-343-1	BIOPSY-FCPS, INSERT ONLY, F. RF245-343SEMI RIGID, OVAL, SERR., DOUBLE ACTION	404935646596	6	Ir	TD-100
RF245-401	BIOP.-FORCEPS,FLEX.,OVAL,SERR.5 FR/1,6 MM,WL 400 MM,DOUBLE ACTION	404935610199	6	Ir	TD-100
RF245-403	BIOP.-FCPS,SEMI-RIGID,OVAL,SERR.5 FR/1,6 MM,WL 400 MM,DOUBLE ACTION	404935610147	6	Ir	TD-100
RF245-601	BIOP.-FORCEPS,FLEX,OVAL,SERR.,DOUBLE ACT5 FR/1,6 MM,WL 600 MM	404935610200	6	Ir	TD-100
RF245-603	BIOP.-FCPS,SEMI-RIGID,OVAL,SERR.5 FR/1,6 MM,WL 600 MM,DOUBLE ACTION	404935610148	6	Ir	TD-100
RF246-401	BIOP.-FCPS,FLEX.,OVAL,SERR.,DOUBLE ACT.6 FR/2,1 MM,WL 400 MM	404935610202	6	Ir	TD-100
RF247-401	BIOP.-FCPS,FLEX.,OVAL,SERR.,DOUBLE ACT7 FR/2,3 MM,WL 400 MM	404935610205	6	Ir	TD-100
RF247-403	BIOP.-FCPS,SEMI-RIGID,OVAL,SERR.7 FR/2,3 MM,WL 400 MM,DOUBLE ACTION	404935610153	6	Ir	TD-100
RF253-281	GRASPING FCPS.,FLEX.,ALLIGATOR JAW,D.ACT3 FR/1,0 MM,WL 280 MM	404935620022	6	Ir	TD-100
RF253-283	GRASPING FCPS.,SEMI-RIGID,ALLIGATOR JAW3 FR/1,0 MM,WL 280 MM,DOUBLE ACTION	404935619993	6	Ir	TD-100
RF253-601	GRASPING FCPS.,FLEX.,ALLIGATOR JAW3 FR/1,0 MM,WL 600 MM,DOUBLE ACTION	404935620025	6	Ir	TD-100
RF255-343	GRASPING FCPS.,SEMI-RIGID,ALLIGATOR JAW5 FR/1,6 MM,WL 340 MM,DOUBLE ACT.,RIGID	404935619997	6	Ir	TD-100
RF255-401	GRASPING FCPS.,FLEX.,ALLIGATOR JAW5 FR/1,6 MM,WL 400 MM,DOUBLE ACTION	404935620027	6	Ir	TD-100
RF255-403	GRASPING FCPS.,SEMI-RIGID,ALLIGATOR JAW5 FR/1,6 MM,WL 400 MM,DOUBLE ACTION	404935619999	6	Ir	TD-100

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REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
RF255-601	GRASPING FCPS.,FLEX.,ALLIGATOR JAW5 FR/1,6 MM,WL 600 MM,DOUBLE ACTION	404935620028	6	Ir	TD-100
RF255-603	GRASPING FCPS.,SEMI-RIGID,ALLIGATOR JAW5 FR/1,6 MM,WL 600 MM,DOUBLE ACTION	404935620000	6	Ir	TD-100
RF257-401	GRASPING FCPS.,FLEX.,ALLIGATOR JAW7 FR/2,3 MM,WL 400 MM,DOUBLE ACTION	404935620030	6	Ir	TD-100
RF257-403	GRASPING FCPS.,SEMI-RIGID,ALLIGATOR JAW7 FR/2,3 MM,WL 400 MM,DOUBLE ACTION	404935620002	6	Ir	TD-100
RF259-401	GRASPING FCPS.,FLEX.,ALLIGATOR JAW9 FR/3,0 MM,WL 400 MM,DOUBLE ACTION	404935620033	6	Ir	TD-100
RF259-403	GRASPING FCPS.,SEMI-RIGID,ALLIGATOR JAW9 FR/3,0 MM,WL 400 MM,DOUBLE ACTION	404935620005	6	Ir	TD-100
RF264-603	GRASPING FCPS.,SEMI-RIGID,SERR.,D.ACT.4 FR/1,2 MM,WL 600 MM,8 MM JAW	404935647883	6	Ir	TD-100
RF265-341	GRASPING FCPS.,FLEX.,SERR.,DOUBLE ACTION5 FR/1,6 MM,WL 340 MM	404935620035	6	Ir	TD-100
RF265-343	GRASPING FCPS.,SEMI-RIGID,SERR.5 FR/1,6 MM,WL 340 MM,DOUBLE ACTION	404935620007	6	Ir	TD-100
RF265-343-1	GRASPING FCPS.,INSERT ONLY, SEMI-RIGID,DOUBLE ACTION ,5 FR/1,6 MM,WL 340 MM	404935646247	6	Ir	TD-100
RF265-401	GRASPING FCPS.,FLEX.,SERR.,DOUBLE ACTION5 FR/1,6 MM,WL 400 MM,8 MM JAW	404935620036	6	Ir	TD-100
RF265-403	GRASPING FCPS.,SEMI-RIGID,SERR.,D.ACT.5 FR/1,6 MM,WL 400 MM,8 MM JAW	404935620008	6	Ir	TD-100
RF265-601	GRASPING FCPS.,FLEX.,SERR.,DOUBLE ACT.5 FR/1,6 MM,WL 600 MM,8 MM JAW	404935620037	6	Ir	TD-100
RF265-603	GRASPING FCPS.,SEMI-RIGID,SERR.,D.ACT.5 FR/1,6 MM,WL 600 MM,8 MM JAW	404935620009	6	Ir	TD-100
RF305-601	DORMIA STONE EXTRACTOR,COMPLETE5 CHARR./1,6 MM,NL 600 MM	404935603099	6	Ir	TD-100

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REF	Item Description	GTIN	rule MDR	class MDR	TD_NO
RS140-000	HANDLE, METAL, WITHOUT RATCHET, ROTATABLE	404935618704	6	Ir	TD-100
RS150-000	HANDLE, METAL, WITH RATCHET, ROTATABLE	404935618705	6	Ir	TD-100
RZ352-001	SEALING CAP, FOR LAP-NEEDLE HOLDERS AND HANDLES WITH LUER-LOCK CONNECTION, LP352-XXX - LP357-XXX	404935647900	6	Ir	TD-100