

Declaration of Conformity Konformitätserklärung

We / Wir

RUDOLF Medical GmbH + CO. KG

**Zollerstrasse 1
78567 Fridingen
Germany**

SRN: DE-MF-000005515

declare under our sole responsibility that the following products

erklären in alleiniger Verantwortung, dass die unten aufgeführten Artikel

Basic UDI-DI	Device	EMDN	Risk Class
4049356TD-025H6	Cable high frequency	Z12010980	1

See attached device list. / *Siehe angehängte Artikelliste.*

with the intended purpose / mit der Zweckbestimmung

<p>HF surgery cables are intended to transmit electrical current from the output of a HF generator to the instrument or to the connector of a neutral electrode at the generator.</p> <p>The cables must be used only with compatible HF generators and instruments. The combination possibilities depend on the corresponding connection types at the generator and instruments.</p>	<p><i>Kabel für HF-Operationen sind für die Übertragung des elektrischen Stroms vom Ausgang eines HF-Generators zum Instrument oder zum Anschluss einer Neutralelektrode am Generator bestimmt.</i></p> <p><i>Die Kabel dürfen nur mit kompatiblen HF-Generatoren und Instrumenten verwendet werden. Die Kombinationsmöglichkeiten hängen von den entsprechenden Anschlussarten an Generator und Instrumenten ab.</i></p>
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are in conformity with the requirements of the

mit den folgenden Anforderungen übereinstimmen:

**Medical Device Regulation (EU)
2017/745 Article 19, Annexes II and III**

**Medizinprodukte-Verordnung (EU) 2017/745
Artikel 19 und Anhängen II und III**

This Declaration of Conformity is valid until 19.05.2030 (DD.MM.YYYY).

Diese Konformitätserklärung ist gültig bis 19.05.2030 (TT.MM.JJJJ).

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Signature:


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TD-025 - cables high-frequency

REF	Item Description	GTIN	GMDN-No	GMDN-Term	Rule MDR	Class MDR	TD No.
HF300-110	HF-MONOPOLAR CONNECT. CABLE,D.5MM,L4,5MF.INST. TO ERBE ACC/ICC/STORZ EQUIPMENT	404935618545	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-120	HF-MONOPOLAR CONNECT. CABLE,D.8MM,L4,5MF.INST. TO VALLEYLAB/CONMED EQUIPMENT	404935618546	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-130	HF-MONOPOLAR CONNECT. CABLE,D.4MM,L4,5MF.INST. TO EQUIPMENT W. 4MM BANANA PLUG	404935618547	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-151	CABLE WITH SAFETY SHEATS FORRUDOLF/BERCHTOLD/MARTIN/ERBE T-GERÄTELENGTH 3.5 M	404935604557	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-152	CABLE WITH SAFETY SHEATS FORERBE ACC/ICCLENGTH 3.5 M	404935604558	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-153	CABLE WITH SAFETY SHEATS FORVALLEYLAB,CONMED,BOVIE UNITSLENGTH 3.5 M	404935604559	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-163	HF-CABLE, MONOPOLAR3 METER, Ø4 MM SOCKETFOR ERBE T-SERIE, MARTIN	404935647891	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-165	HF-CABLE, MONOPOLAR5 METER, Ø4 MM SOCKETFOR ERBE T-SERIE, MARTIN	404935647892	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-173	HF-CABLE, MONOPOLAR3 METER, Ø4 MM SOCKETFOR VALLEYLAB	404935647893	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-175	HF-CABLE, MONOPOLAR5 METER, Ø4 MM SOCKETFOR VALLEYLAB	404935647894	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-183	HF-CABLE, MONOPOLAR3 METER, Ø4 MM SOCKETFOR MARTIN	404935647895	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025

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REF	Item Description	GTIN	GMDN-No	GMDN-Term	Rule MDR	Class MDR	TD No.
HF300-185	HF-CABLE, MONOPOLAR5 METER, Ø4 MM SOCKETFOR MARTIN	404935647896	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-193	HF-CABLE, MONOPOLAR3 METER, Ø4 MM SOCKETFOR ERBE ACC/ICC	404935647897	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-195	HF-CABLE, MONOPOLAR5 METER, Ø4 MM SOCKETFOR ERBE ACC/ICC	404935647898	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-202	CABLES F. BIPOLAR SCISSORFOR ERBE, 3 METER	404935626301	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-204	CABLES F. BIPOLAR SCISSORF. MARTIN, BERCHTOLD, AESCULAP, 3 METER	404935626303	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF300-206	CABLES F. BIPOLAR SCISSORFOR VALLEYLAB, EMC, 3 METER	404935626305	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-011	CABLE FOR ELECTRODE HANDEL HF410-0114 METER ERBE COMPATIBLE ICC/ACC	404935646914	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-012	CABLE FOR ELECTRODE HANDEL HF410-0114 METER ERBE COMPATIBLE ICC/ACC(10/PKG.)	404935646915	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-015	CABLE FOR ELECTRODE HANDEL HF410-0154 METER MARTIN/BERCHTOLD COMPATIBLE	404935646916	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-104	HF-CABLE, BIPOLAR, PLUG WITH FLEXIBLEJOINT, FLAT-PLUG INSTR. SIDE, 4M	404935647880	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-113	CABLES F. BIPOLAR INSTR.,FLAT PLUG, 3 METER	404935617741	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025

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REF	Item Description	GTIN	GMDN-No	GMDN-Term	Rule MDR	Class MDR	TD No.
HF310-123	CABLES F. BIPOLAR INSTR.,FLAT PLUG,3 METER	404935617743	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-125	CABLES F. BIPOLAR INSTR.,FLAT PLUG,5 METER	404935617744	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-133	CABLES F. BIPOLAR INSTR.,FLAT PLUG,3 METER	404935617745	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-135	CABLE F. BIPOLAR INSTR.,FLAT PLUG,5 METER	404935617746	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-3031	CABLE FOR BIPOLAR INSTRUMENTS2- PIN PLUG, U20 PLUG, 2X4 MM4M	404935646917	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025
HF310-333	CABLES F. BIPOLAR INSTR.,2-PIN-PLUG,3M	404935617757	47487	Electrical-only medical device connection cable, reusable	1	I	TD-025