

Konformitätserklärung / Declaration of Conformity

RUDOLF Medical GmbH + CO. KG

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Wir erklären hiermit in alleiniger Verantwortung, dass unsere Medizinprodukte der Gruppe „Chirurgische Instrumente“ wie folgt gemäß RL 93/42 EWG, Anhang IX klassifiziert wurden

We herewith declare by our own responsibility, that our Medical Devices related to the Product Group „Surgical Instruments“ have been classified according MDD 93/42/EEC, Annex IX,

UMDNS No / UMDNS Nr.	Description	Bezeichnung	Rule / Regel	Category / Kategorie	Class / Klasse
10-174	Applicators, Clip	<i>Applikator, Clip</i>	09	6	I
10-226	Atomizers	<i>Zerstäuber</i>	09	5	I
10-500	Brushes	<i>Bürste</i>	09	1	I
10-519	Burs	<i>Bohrer</i>	04	1	I
10-718	Catheters, Eustachian	<i>Katheter, Ohrtrompete</i>	09	5	I
10-762	Catheters, Urethral	<i>Katheter, Harnröhre</i>	09	5	I
10-824	Chisels	<i>Meißel</i>	09	6	I
10-829	Chisels, Orthopedic	<i>Meißel, orthopädisch</i>	09	6	I
10-868	Clamps, Bulldog	<i>Klemme, Bulldog</i>	09	6	I
10-870	Clamp, haemorrhoidal	<i>Klemme, hämorrhoidal</i>	09	6	I
10-902	Clips, Drape	<i>Clip, Tuch</i>	09	1	I
10-943	Collectors, Sputum	<i>Sammelgefäß, Auswurf</i>	09	1	I
11-084	Curets	<i>Kürette</i>	09	6	I
11-160	Dental Hand Instruments	<i>Dental-Handinstrument</i>	03	5	I
11-179	Dermatomes	<i>Dermatom</i>	09	6	I
11-263	Dilators, Tracheal	<i>Dilatator, tracheal</i>	09	6	I
11-266	Dilator, uterine	<i>Dilatator, uterus</i>	09	5	I
11-268	Dilators, Vascular	<i>Dilatator, vaskulär</i>	09	6	I
11-290	Dissectors	<i>Sezierer</i>	09	6	I
11-291	Distractors	<i>Distraktor</i>	09	6	I
11-504	Elevators	<i>Elevatorium</i>	09	6	I
11-587	Enucleators	<i>Enukleator</i>	09	6	I
11-701	Files	<i>Feile</i>	09	6	I
11-704	Filiforms	<i>Fadeninstrument</i>	09	9	I
11-710	Filters	<i>Filter</i>	05	1	I
11-726	Fittings/Adapters	<i>Anschlüsse/Adapter</i>	09	1	I
11-729	Fittings/Adapters, Luer	<i>Anschlüsse/Adapter, Luer-Lock</i>	09	1	I
11-774	Forceps	<i>Zange</i>	09	6	I

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11-775	Forceps, Biopsy	Zange, Biopsie	09	6	I
11-797	Forceps, Tissue	Zange, Gewebe	09	6	I
11-822	Gags	Mundsperr	09	5	I
11-835	Carriers, Medical Device	Geräteträger, Medizingerät	05	1	I
11-930	Guides, Drill	Führung, Bohrer	09	6	I
11-963	Headlights	Stirnleuchte	04	1	I
12-028	Hooks	Haken	09	6	I
12-035	Hooks, Skin	Haken, Haut	09	6	I
12-038	Hooks, Tracheal	Haken, tracheal	09	6	I
12-236	Knife Holders	Messerhalter	09	1	I
12-239	Knives	Messer	09	6	I
12-240	Knives, Amputating	Messer, Amputation	09	6	I
12-252	Knives, Scalpel	Messer, Skalpell	09	1	I
12-319	Lens Loops	Starschlinge	09	6	I
12-321	Lens Spoons	Starlöffel	09	6	I
12-340	Light Sources	Lichtquelle	09	12	I
12-374	Lingual Palatal Bars	Zungen-Gaumen-Spatel	09	5	I
12-421	Mallets	Hammer	09	1	I
12-440	Markers	Marker	09	1	I
12-547	Mirrors	Spiegel	09	1	I
12-549	Mirrors, Laryngeal	Spiegel, laryngeal	09	5	I
12-726	Needle Holders	Nadelhalter	09	6	I
12-729	Needles	Nadel	09	1	I
12-844	Osteotomes	Osteotom	09	6	I
12-986	Percussors	Perkussionshammer	09	6	I
12-989	Perforators	Perforationsinstrument	09	6	I
13-043	Pinwheels	Sensibilitätsmesser	09	1	I
13-117	Probes	Sonde	09	6	I
13-228	Punches	Stanze	09	6	I
13-230	Punches, Biopsy	Stanze, Biopsie	09	6	I
13-288	Rasps	Raspel	09	6	I
13-368	Retainers	Fixierung	09	1	I
13-373	Retractors	Wundhaken	09	6	I
13-416	Rongeurs	Hohlmeißelzange	09	6	I
13-447	Blades, Saw	Klinge, Säge	09	6	I
13-448	Saws	Säge	09	6	I
13-480	Scissors	Schere	09	6	I
13-517	Screwdrivers, Bone	Schraubendreher, Knochen	09	6	I
13-858	Supports	Stütze	09	1	I
13-630	Snares	Schlingeninstrument	09	6	I
13-631	Snares, Polyp	SCHLINGENINSTRUMENT, Polyp	04	9	I
13-644	Sounds, Uterine	Untersuchungssonde, Uterus	09	6	I
13-645	Spatulas	Spatel	09	6	I

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13-649	Spatulas, Lung	<i>Spatel, Lunge</i>	09	6	I
13-664	Specula, Nasal	<i>Spekulum, Nase</i>	09	5	I
13-707	Spreaders	<i>Spreizer</i>	09	6	I
13-730	Sterilization Containers	<i>Sterilgutcontainer</i>	05	1	I
13-750	Stethoscopes	<i>Stethoskop</i>	09	1	I
13-764	Stimulators, Auditory	<i>Stimulator, Gehör</i>	09	1	I
13-827	Strippers, Tendon	<i>Stripper, Sehne</i>	09	6	I
13-828	Stripper, Vein	<i>Stripper, Vene</i>	09	6	I
13-936	Syringes, Catheter	<i>Spritze, Katheter</i>	09	1	I
14-070	Tonsillectomes	<i>Tonsillektomie-Instrument</i>	09	6	I
14-105	Traction Units	<i>Extensionseinheit</i>	09	1	I
14-146	Trephines	<i>Trephine</i>	09	6	I
14-227	Tubes, Rectal	<i>Tubus, rektal</i>	09	5	I
14-238	Tubing	<i>Schlauch</i>	09	1	I
14-255	Tuning Forks	<i>Stimmgabel</i>	09	1	I
14-257	Tweezers	<i>Pinzette</i>	09	6	I
14-286	Bougies, Urethral	<i>Bougie, Harnröhre</i>	09	5	I
15-212	Clamps, Other	<i>Klemme, sonstige</i>	09	1	I
15-215	Dilators, Other	<i>Dilatator, sonstige</i>	09	6	I
15-221	Forceps, Other	<i>Zange, sonstige</i>	09	6	I
15-224	Guides, Other	<i>Führung, sonstige</i>	09	7	I
15-226	Knives, Other	<i>Messer, sonstige</i>	09	6	I
15-237	Probes, Other	<i>Sonde, sonstige</i>	09	6	I
15-249	Spatulas, Other	<i>Spatel, sonstige</i>	09	6	I
15-252	Sponges, Other	<i>Tupfer, sonstige</i>	09	1	I
15-256	Syringes, Other	<i>Spritze, sonstige</i>	09	1	I
15-266	Shields, X-ray, Other	<i>Schutzschild, Röntgen, sonstige</i>	09	1	I
15-308	Cables, Fiberoptic	<i>Kabel, faseroptisch</i>	09	1	I
15-561	Bowls	<i>Schale</i>	05	1	I
15-572	Cups	<i>Becher</i>	09	1	I
15-580	Extractor	<i>Extraktor</i>	09	6	I
15-594	Racks	<i>Gestell</i>	09	1	I
15-602	Specula	<i>Spekulum</i>	09	6	I
15-609	Trays	<i>Tablett</i>	09	1	I
15-652	Loupes	<i>Lupe</i>	09	1	I
15-670	Forceps, Bone	<i>Zange, Knochen</i>	09	6	I
15-671	Clamps, Rectal	<i>Klemme, rektal</i>	09	6	I
15-677	Elevators, Uterine	<i>Elevatorium, Uterus</i>	09	6	I
15-689	Applicators, other	<i>Applikator, sonstige</i>	09	6	I
15-741	Rasps, Bone	<i>Raspel, Knochen</i>	09	6	I
15-868	Needle Guides	<i>Nadelführung</i>	09	6	I
15-882	Clamps, Vascular	<i>Klemme, Gefäß</i>	09	6	I
16-028	Clips, Vascular	<i>Clip, Gefäß</i>	10	6	I

UMDNS No / UMDNS Nr.	Description	Bezeichnung	Rule / Regel	Category / Kategorie	Class / Klasse
16-052	Clips, Ligating	Clip, unterbindend	09	6	I
16-055	Screws	Schraube	09	6	I
16-155	Obturator, Endoscopic	Verschlussinstrument, endoskopisch	09	6	I
16-268	Forceps, Biopsy, Flexible	Zange, Biopsie, flexible Endoskopie	09	6	I
16-269	Forceps, Biopsy, Rigid Endoscopic	Zange, Biopsie, starre Endoskopie	09	6	I
16-340	Cast Cutters, Electric	Gipssäge, elektrisch	04	12	I
16-429	Catheters, Cholangiography	Katheter, Cholangiographie	09	6	I
16-444	Appliers, Cerclage, Orthopedic	Applizierer, Cerclage, orthopädisch	09	6	I
16-467	Wire Bending Dies, ENT	Draht-Biegeform, HNO	09	1	I
16-501	Medical Gas Cylinders	Gasflasche, medizinisch	09	1	I
16-633	Spoons, Medicine	Löffel, Medikamente	09	1	I
16-767	Containers	Container	09	1	I
16-771	Staples	Klammer	09	1	I
16-870	Excavators	Exkavator	09	6	I
16-980	Probes, Arthroscopy	Sonde, Arthroskopie	09	6	I
17-633	Urethrotomes	Urethrotom	09	5	I
17-675	Approximators, Vessel	Approximator, Gefäß	09	6	I
18-882	Clamps, Vascular	Klemme, Gefäß	09	6	I

und unter Berücksichtigung folgender Richtlinie gefertigt wurden:
have been manufactured under consideration of following Council Directive:

EG-Richtlinie 93/42/EWG European Medical Device Directive 93/42/EEC, annex IX

Die gelisteten Produkte sind konform mit den grundlegenden Anforderungen des Anhang I der EG-Richtlinie 93/42/EWG und werden somit mit **CE** gekennzeichnet und von uns in Verkehr gebracht.

*The listed products are conformal to the essential requirements of the Medical Device Directive 93/42/EEC Annex I and are therefore placed into market marked with **CE** by us.*

Das Konformitätsbewertungsverfahren wurde in alleiniger Verantwortung gemäß EG RL 93/42/EWG, Anhang II durchgeführt.

The conformity assessment has been performed under sole responsibility according to MDD 93/42/EEC, Annex II

15.10.2018

Datum

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Diese Erklärung ist für die durch DMR-001 regulierten Produkte bis zum 29.04.2020 gültig.
This declaration is valid for the products regulated by DMR-001 till 29 April 2020.