INSTRUMENTE GMBH

Konformitätserklärung
Declaration of Conformity

Wir,
We,

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erklärt hiermit unter eigener Verantwortung, dass alle Artikel der Produktgruppe
herewith declare under our own responsibility, that all items of the product group

Instrumente und Geräte für die Chirurgie der Klasse I, IIa + IIb
Gemäß unseren Katalogen Standard Chirurgische Instrumente, Titan Instrumente, Neuro Chirurgie Instrumente, Steril Container, Endoskope und Zubehör für flexible und starre Endoskopie

Instruments and Equipment for surgery of Class I, IIa + IIb
In refer to our catalogues General Surgical Instruments, Titanium Instruments, Neuro Surgery Instruments, Sterilization Containers, Endoscopes and Accessories for flexible and rigid Endoscopy

Reg. No.	Bezeichnung	Description	Risikoklasse	UMDNS	GMDN
DE/CA39/11/E172	Lichtquelle	light source	KL I	12-340	12340
DE/CA39/11/E173	Gipssäge, elektrisch	cement-saw electric	KL I	16-340	16340
DE/CA39/11/E174	Video-System, Endoskopie	video-system, endoscopy	KL I	15-967	15967
DE/CA39/833/100	Sonde	probes	KL I	13-117	13117
DE/CA39/833/101	Raspel Nase	rasps nasal	KL I	13-290	35296
DE/CA39/833/102	Wundhaken	retractors	KL I	13-373	13373
DE/CA39/833/118	Schraubendreher Knochen	screwdrivers bone	KL I	13-517	33968
DE/CA39/833/124Ä	Tupferstab, Gaze	gaze	KL I	15-047	15047

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DE/CA39/833/126	Stethoskop	stetoscope	KL I	13-750	13750
DE/CA39/833/128	Stripper Sehne	strippers tendon	KL I	13-827	35380
DE/CA39/833/130	Gürtel Extension	Extension device	KL I	14-100	33653
DE/CA39/833/131	Stimmgabel	tuning forks	KL I	14-255	32526
DE/CA39/833/132	Pinzette	tweezers	KL I	14-257	35420
DE/CA39/833/134	Container	Container	KL I	16-767	16767
DE/CA39/833/137	Approximator	approximators	KL I	17-673	17673
DE/CA39/833/138	Amniotom	amniotomes	KL I	10-089	10089
DE/CA39/833/13Ä1	Elektrode, HF-Chirurgie	electrodes, HF-surgery	KL II B	15-579	15579
DE/CA39/833/143	Katheter-Einführung	catheter introducers	KL I	10-678	10678
DE/CA39/833/150	Clip Kopfhaut	Clip Scalp	KL I	10-909	10898
DE/CA39/833/152	Kompressor	compressors	KL I	10-971	31253
DE/CA39/833/153	Dilatator	dilators	KL I	11-254	11254
DE/CA39/833/157	Elevatorium	elevators	KL I	11-504	11504
DE/CA39/833/165	Zange Instrumente	forceps utility	KL I	11-798	35079
DE/CA39/833/166	Haken	hooks	KL I	12-028	35105
DE/CA39/833/173	Tablett Instument	trays instrument	KL I	12-143	12143
DE/CA39/833/178	Ligator Hämorrhoidal	ligator hemorrhoidal	KL I	12-335	35157
DE/CA39/833/179	Zungen-Gaumen-Spatel	lingual palatal bars	KL I	12-374	13645
DE/CA39/833/180	Becher	cups	KL I	15-572	15572
DE/CA39/833/181	Spiegel laryngeal	mirrors laryngeal	KL I	12-549	33431
DE/CA39/833/186	Stanze	punches	KL I	13-228	35284
DE/CA39/833/189Ä1	Anoskop	anoscopes	KL II A	10-156	10156
DE/CA39/833/191Ä1	Amnioskop	Amnioscope	KL II A	10-088	34837
DE/CA39/833/192Ä2	Schere	scissors	KL I	13-480	35325
DE/CA39/833/199	Tasterzirkel, Sonstige	compasses	KL I	16-417	30123
DE/CA39/833/20	Bürste, Chirurgische Desinfektion	brushes surgical scrub	KL I	10-507	34882
DE/CA39/833/21	Meißel	chisels	KL I	10-824	10824
DE/CA39/833/217	Schlingeninstrument	snares	KL I	13-630	34822
DE/CA39/833/221	Spatel	spatulas	KL I	13-645	13645

DE/CA39/833/225	Spreizer	spreaders	KL I	13-707	13707
DE/CA39/833/227	Sterilgutcontainer	sterilization containers	KL I	13-730	13730
DE/CA39/833/230	Zungen-Depressor	Tounge-depressors	KL I	14-066	14066
DE/CA39/833/234	Trephine	trephines	KL I	14-146	14146
DE/CA39/833/239	Reinigungsgerät Reinigungspistole	Cleaners	KL I	15-013	12300
DE/CA39/833/24	Klemme	clamps	KL I	10-861	10861
DE/CA39/833/246	Führung sonstige	Guide other	KL I	15-224	37150
DE/CA39/833/253	Augenmagnet	Eye magnet	KL I	15-269	35495
DE/CA39/833/256	Schale	bowls	KL I	15-561	15561
DE/CA39/833/257	Spekulum	speculas	KL I	15-602	35517
DE/CA39/833/264	Sonde, Mikrolaryngeal	probes microlaryngeal	KL I	15-877	35592
DE/CA39/833/287	Perkussionshammer	persussors	KL I	12-986	35235
DE/CA39/833/269	Fremdkörpernadel	spuds eye	KL I	16-025	16025
DE/CA39/833/270	Hülse	Sleeve Tisue screw holding sleeve	KL I	16-146	15571
DE/CA39/833/A363	Kabel/Leitung, HF-Chirurgiegerät	HF- connecting cables	KL I	11-496	35042
DE/CA39/833/276	Brille	Glasses	KL I	11-677	11677
DE/CA39/833/277	Stripper, Vene	Strippers, vein	KL I	13-828	35377
DE/CA39/833/280Ä	Arthroskop	Arthroscopes	KL II A	10-198	34856
DE/CA39/833/289Ä	Zystoskop, starr	Cystoscope, rigid	KL II A	17-145	17145
DE/CA39/833/290	Zerstäuber	powder blowers	KL I	10-226	10226
DE/CA39/833/292	Mundsperre	Gags	KL I	11-822	35085
DE/CA39/833/30	Clip-Applizierer	Clip-Applier	KL I	10-894	34955
DE/CA39/833/305	Chirurgie-Instrumente-Containersystem	Surgical instrument container system	KL I	16-349	13730
DE/CA39/833/306	Fangkörbchen Harnstein	retrievel basket urological stones	KL I	17-574	35808
DE/CA39/833/308Ä	Laparoskop	laparoscope	KL II A	12-291	12291
DE/CA39/833/31	Clip-Entferner	clip removers	KL I	10-895	10895
DE/CA39/833/312	Wundhakenhalter chirurgisch, automatisch	retractor holders surgical, automatic	KL I	17-107	35967
DE/CA39/833/314Ä	Elektrode, HF-Chirurgie	Electrodes, electrosurgical	KL II B	15-579	15579
DE/CA39/833/320	Anschlüsse / Adapter	Connectors / Adapters	KL I	11-726	35074
DE/CA39/833/324	Kabel, faseroptisch	cable fiberoptic	KL I	15-308	35507

DE/CA39/833/326	Spritze, Mikro-	syringe micro	KL I	16-878	13929
DE/CA39/833/327	Nasopharyngoskop	Nasopharyngoscope	KL I	12-709	13011
DE/CA39/833/329Ä1	Proktosigmoidoskop	proktosigmoidoscope	KL II A	13-127	13127
DE/CA39/833/331	Spektrometer, Masse, Labor	Spectrometers, Mass, Laboratory	KL I	17-199	35883
DE/CA39/833/332	Endoskopie Kamera-Adapter	endoscopy camera-adapter	KL I	18-104	36292
DE/CA39/833/333Ä	Rhinoskop	Rhinoscope	KL II A	13-396	35316
DE/CA39/833/338	Blasenkatheterisierungs-/Urinsammelkitt	catheters	KL I	14-292	10685
DE/CA39/833/339Ä	Hysteroskop	Hysteroscope rigid	KL II A	12-081	36628
DE/CA39/833/340	Fangkörbchen	retrievel basket stones a.foreign bodies	KL I	15-573	35808
DE/CA39/833/342	Urethrotom	Urethrotome	KL I	17-633	17633
DE/CA39/833/347	Kanüle, -sonstige	Cannula, other	KL II A	15-206	
DE/CA39/833/35	Clip-Wunde	Clip	KL I	10-916	
DE/CA39/833/354	Elektrode, HF-Chirurgie,Aktivelektrode	Elektrode HF-Surgery, active electrode	KL II B	16-860	42553
DE/CA39/833/357	Ahle	awls	KL I	15-275	15275
DE/CA39/833/358Ä	Trokar	trocar	KL II A	14-154	14154
DE/CA39/833/359	Zange, Greif, flexible Endoskopie	forceps Endoscopy	KL I	15-628	
DE/CA39/833/36	Kürette	Curettes	KL I	11-084	34980
DE/CA39/833/360	Blutdruckmessgerät, aneroid	Blood pressure meter	KL I	16-156	
DE/CA39/833/361	Fixierung	fixation	KL I	13-368	
DE/CA39/833/362	Extraktor, Nagel	Ectractor nail	KL I	12-696	
DE/CA39/833/365	Thorakoskop	Thorakoscope	KL II A	14-047	
DE/CA39/833/366	Nephroskop, starr	Nephroscope, rigid	KL II A	15-290	15290
DE/CA39/833/367	Starrendoskop	Stiff endoscope	KL II A	11-274	
DE/CA39/833/368	Ureterorenoskop	Ureterorenoscope	KL II A	17-690	17690
DE/CA39/833/369	Anschlüsse / Adapter	Connectors / Adapters	KL II A	11-726	11726
DE/CA39/833/370	Reihbale, orthopädisch	Reamer, orthopedic	KL II A	13-297	13297
DE/CA39/833/371	Säge, Knochen	Saw, bone	KL II A	13-449	13449
DE/CA39/833/373	Klammer, Knochen	Clip, bone	KL II B	16-103	16103
DE/CA39/833/A374	Zange, Elektrochirurgie	Bipolar forceps for coagulation	KL II B	11-502	11502
DE/CA39/833/37	Dermatom	dermatomes	KL I	11-179	11179

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DE/CA39/833/40	Dissektionskit	Post Mortem Set	KL I	11-289	11289
DE/CA39/833/44	Handbohrer/ -Dreher	Handdrill / handdriver	KL I	11-345	11345
DE/CA39/833/48	Feile	file	KL I	11-701	11701
DE/CA39/833/53Ä	Messer , Sonstige	knives others	KL I	15-226	35130
DE/CA39/833/55	Säge, Sonstige	Saw other	KL I	15-244	34821
DE/CA39/833/372	Bohrer, orthopädisch	Burs, orthopedic	KL II B	17-995	36249
DE/CA39/833/76	Kopfspiegel	head mirrors	KL I	11-960	31106
DE/CA39/833/78	Klinge Messer	blades knife	KL I	12-234	15558
DE/CA39/833/79	Messerhalter	knife holders	KL I	12-236	12236
DE/CA39/833/87Ä	Laryngoskop	Laryngoscope	KL II A	12-293	12293
DE/CA39/833/89	Hammer, Knochen	malllets bone	KL I	12-423	32312
DE/CA39/833/90	Nadelhalter	needle holders	KL I	12-726	12726
DE/CA39/833/92	Nadel	needles	KL I	12-729	12729
DE/CA39/833/94	Ophthalmoskop direkt	ophtalmoscope direct	KL I	12-817	12817
DE/CA39/833/95	Ophthalmoskop indirekt	ophtalmoscope	KL I	12-818	12815
DE/CA39/833/97Ä	Otoskop	otoscope	KL II A	12-849	12849
DE/CA39/833/98	Perkussionshammer	percussors	KL I	12-986	35235
DE/CA39/833/282	Insufflationsgerät Hysteroskopie	Insuflator Hysteroscopy	KL IIA	16-848	32682
DE/CA39/833/283	Saug-, Spülgerät	suction / irrigation tubes	KL IIA	13-845	36671
DE/CA39/833/285	Schlauch	tubes	KL IIA	14-238	14238
DE/CA39/833/296	Katheter Cholangiographie	catheter cholangiography	KL IIA	16-429	16429
DE/CA39/833/04Ä	Draht Knochen	Wire, bone	KL IIB	16-104	35685
DE/CA39/833/05Ä	Schraube, Knochen	Screw, bone	KL IIB	16-101	16101
DE/CA39/833/06Ä	Platte Knochen	Plate, bone	KL IIB	13-050	35241
DE/CA39/833/07Ä	Nagel Knochen	Nail, Bone	KL IIB	16-078	16078
DE/CA39/833/10Ä1	Elektrode, HF-Chirurgie, Aktivelektrode	Electrodes, electrosurgical, active, foe	KL II B	16-206	42553
DE/CA39/833/11Ä	Elektrodenhalter, HF-Chirurgie	Electrode holders, electrosurgical	KL IIB	11-497	35043
DE/CA39/833/315	Schere Endoskopie	Scissors endoscopic	KL IIB	13-484	35326

klassifiziert gemäß RL 93/42/EWG (M5), Anhang IX, Regel 2, 6, 7 und 11 in Risikoklasse I, IIa + IIb
classified according to MDD 93/42/EEC (M5) annex IX rule 2, 6, 7 and 11 into risk class I, IIa + IIb

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

EG-Richtlinie 93/42/EWG (M5)
European Medical Device Directive 93/42/EEC (M5)

Angewandtes Konformitätsbewertungsverfahren nach Richtlinie 93/42/EWG (M5), Anhang II.
Die gelisteten Produkte sind konform mit den Grundlegenden Anforderungen des Anhang I der EG-Richtlinie 93/42/EWG (M5) und werden somit
mit CE bzw CE**0297** gekennzeichnet, von uns in Verkehr gebracht
Das Konformitätsbewertungsverfahren wurde durch unsere Benannte Stelle DQS GmbH, Frankfurt, Notified Body Code 0297 durchgeführt.

Applied conformity assessment according Annex II of MDD 93/42/EEC (M5).
*The listed products are conform to the essential requirements of the Medical Device Directive 93/42/EEC (M5) Annex I and are therefore placed into market with CE or with CE**0297** by us.*
The conformity assessment has been performed by our notified body DQS GmbH, Frankfurt, notified body code 0297.

Tuttlingen, January 2016

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Diese Erklärung ist gültig bis 2018-05-16 / This declaration is valid until 2018-05-16

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