



EG-Konformitätserklärung EC-Declaration of conformity

Gemäß EG-Richtlinie 93/42/EWG
Acc. MDD 93/42/EEC

Wir
We

CEATEC Medizintechnik GmbH
Untere Hauptstr.6
78573 Wurmlingen

erklären in alleiniger Verantwortung, dass folgende Medizinprodukte
herewith declares under sole responsibility, that following medical devices

UMDNS	Beschreibung <i>Description</i>	Regel <i>Rule</i>	Klasse <i>Class</i>
10-088	Amnioskop <i>Amnioscope</i>	5	I
10-176	Applikator, proktoskopisch <i>Applicators, Proctoscopic</i>	5	I
10-500	Bürste <i>Brushes</i>	1	I
10-561	Kanüle <i>Cannula</i>	6	I
10-564	Kanüle, arteriell <i>Cannulae, Arterial</i>	6	I
10-566	Kanüle, Absaugung <i>Cannulae, Asplting</i>	6	I
10-578	Kanüle, Sinus <i>Cannulae, Sinus</i>	5	I
10-678	Katheter, Einführung <i>Catheter Introducers</i>	5	I
10-718	Katheter, Ohrtrompete <i>Catheter, Eustachian</i>	5	I
10-764	Katheter, Harnwege <i>Catheter, Urinary</i>	5	I
10-824	Meißel <i>Chisels</i>	6	I
10-825	Meißel, Knochen <i>Chisels, Bone</i>	6	I
10-861	Klemme <i>Clamps</i>	6	I
10-864	Klemme, Aorta <i>Clamps, Aorta</i>	6	I
10-865	Klemme, Arterie <i>Clamps, Artery</i>	6	I
10-867	Klemme, Bronchus <i>Clamps, Bronchus</i>	6	I
10-868	Klemme, Bulldog <i>Clamps, Bulldog</i>	6	I
10-869	Klemme, Beschneidung <i>Clamps, Clcumcision</i>	5	I
10-871	Klemme, intestinal <i>Clamps, Intestinal</i>	6	I
10-875	Klemme Schlauch <i>Clamps, Tubing</i>	1	I
10-876	Klemme, Nabel <i>Clamps, Umbilical</i>	5	I
10-894	Clip-Applizierer <i>Clip Applicators</i>	6	I
10-895	Clip Entferner <i>Clip Remover</i>	6	I
10-902	Clip, Tuch <i>Clips, Drape</i>	6	I
10-909	Clip, Kopfhaut <i>Clip, Scalp</i>	6	I
10-916	Clip, Wunde <i>Clip, Wound</i>	6	I
11-084	Kürette <i>Curettes</i>	6	I
11-179	Dermatom <i>Dermatomes</i>	6	I
11-259	Dilatator, lakrimal <i>Dilatator, Lacrimal</i>	6	I
11-265	Dilatator, Harnröhre <i>Dilatator, Urethral</i>	5	I
11-266	Dilatator, Uterus <i>Dilatator, Uterine</i>	6	I

11-268	Dilatator, vaskular	<i>Dilatator, Vascular</i>	6	
11-290	Sezierer	<i>Dissectors</i>	6	
11-291	Distraktor	<i>Distractors</i>	6	
11-337	Drillbohrer, Fingernagel	<i>Drills, Fingernail</i>	6	
11-345	Handbohrer/- dreher	<i>Driver/Extractors</i>	1	
11-493	HF-Chirurgiegerät-Adapter, Kabel	<i>Electrosurgical Unit Adapters, Cable</i>	1	
11-504	Elevatorium	<i>Elevators</i>	6	
11-506	Elevatorium, HNO	<i>Elevators, ENT</i>	6	
11-508	Elevatorium, Orthopädie	<i>Elevators, Orthopedic</i>	6	
11-701	Feile	<i>Files</i>	6	
11-702	Feile, Knochen	<i>Files, Bone</i>	6	
11-710	Filter	<i>Filters</i>	1	
11-729	Luer-Lock Anschluss/Adapter	<i>Luer-Lock Connector/Adapter</i>	1	
11-774	Zange	<i>Forceps</i>	6	
11-775	Zange, Biopsie	<i>Forceps, Biopsy</i>	6	
11-782	Zange, Gallenblase	<i>Forceps, Gallbladder</i>	6	
11-785	Zange, intestinal	<i>Forceps, Intestinal</i>	6	
11-788	Zange, Geburtshilfe	<i>Forceps, Obstetrical</i>	5	
11-791	Zange, Tupfer	<i>Forceps, Sponge</i>	6	
11-792	Zange, Sterilgut	<i>Forceps, Sterizier Transfer</i>	1	
11-797	Zange, Gewebe	<i>Forceps, Tissue</i>	6	
11-798	Zange, Instrumente	<i>Forceps, Utility</i>	6	
11-822	Mundsperr	<i>Gags</i>	5	
11-930	Führung, Bohrer	<i>Guides, Drill</i>	1	
11-933	Schneidzange	<i>Guillotines</i>	1	
11-935	Schneidzange, Tonsille	<i>Guillotines, Tonsil</i>	5	
11-958	Kopfhalter	<i>Head holder</i>	6	
12-028	Haken	<i>Hooks</i>	6	
12-034	Haken sklerale Fixation	<i>Hooks, Scleral Fixation</i>	5	
12-036	Haken, Strabismus	<i>Hooks, Strabismus</i>	5	
12-038	Haken tracheal	<i>Hooks, Tracheal</i>	5	
12-143	Tablett, Instrument	<i>Trays, Instrument</i>	1	
12-234	Klinge, Messer	<i>Blades, Knife</i>	6	
12-236	Messerhalter	<i>Knife Holders</i>	1	
12-239	Messer	<i>Myoma-Instrument</i>	6	
12-245	Messer, Ohr	<i>Knives, Ear</i>	5	
12-248	Messer, Meniscus	<i>Knives, Meniscus</i>	6	
12-251	Messer, Gips	<i>Knives, Plaster</i>	1	
12-252	Messer, Skalpell	<i>Knives, Scalpel</i>	6	
12-293	Laryngoskop	<i>Laryngoscope</i>	5	
12-321	Starlöffel	<i>Lens Spoons</i>	6	
12-335	Ligator, Hämorrhoid	<i>Ligator, hemorrhoid</i>	6	
12-336	Fadenführer	<i>Ligature Carriers</i>	1	
12-374	Zungen-Gaumen-Spatel	<i>Lingual Palatal Bars</i>	5	
12-423	Hammer, Knochen	<i>Mallets, Bone</i>	6	
12-440	Marker	<i>Markers</i>	6	

12-442	Marker, okular	<i>Marker, ocular</i>	1	
12-505	Becher, Medikamente	<i>Cups, Medicine</i>	1	
12-547	Spiegel	<i>Mirrors</i>	5	
12-549	Spiegel, laryngeal	<i>Mirrors, Laryngeal</i>	5	
12-695	Schneidegerät, Nagel	<i>Clippers, Nail</i>	1	
12-726	Nadelhalter	<i>Needle Holders</i>	6	
12-729	Nadel	<i>Needles</i>	6	
12-754	Nadel, Wundnaht	<i>Needles, Suture</i>	6	
12-845	Osteotom, orthopädisch	<i>Osteotomes, Orthopedic</i>	6	
12-846	Osteotom, plastische Chirurgie	<i>Osteotomes, Plastic Surgery</i>	6	
12-986	Perkussionshammer	<i>Percussors</i>	1	
13-041	Schneidinstrument, Stift und Draht	<i>Cutters, Pin and Wire</i>	1	
13-117	Sonde	<i>Probes</i>	6	
13-120	Sonde, Auge, lakrimal	<i>Probes, Eye, Lacrimal</i>	6	
13-228	Stanze	<i>Punches</i>	6	
13-229	Punches, Aortic	<i>Punches, Aortic</i>	6	
13-290	Raspel, Nase	<i>Rasps, Nasal</i>	6	
13-297	Reibahle, orthopädisch	<i>Reamers, Orthopedic</i>	6	
13-373	Wundhaken	<i>Retractors</i>	6	
13-375	Wundhaken, abdominal	<i>Retractors, Abdominal</i>	6	
13-376	Wundhaken, Blase	<i>Retractors, Bladder</i>	6	
13-384	Wundhaken, Laminektomie	<i>Retractors, Laminectomy</i>	6	
13-386	Wundhaken, Orthopädie	<i>Retractors, Orthopedic</i>	6	
13-389	Wundhaken, Rippe	<i>Retractors, Rib</i>	6	
13-390	Wundhaken, selbstsperrend	<i>Retractor, self-locking</i>	6	
13-392	Wundhaken, vaginal	<i>Retractors, Vaginal</i>	5	
13-416	Hohlmeißelzange	<i>Rongeurs</i>	6	
13-418	Hohlmeißelzange, Neurochirurgie	<i>Rongeur forceps, neurosurgery</i>	6	
13-447	Klinge, Säge	<i>Blades, Saw</i>	6	
13-451	Säge, Knochen, manuell	<i>Saws, Bone, Manual</i>	6	
13-480	Schere	<i>Scissors</i>	6	
13-481	Schere, Verband	<i>Scissors, Bandage</i>	1	
13-485	Schere, Auge	<i>Scissors, Eye</i>	5	
13-493	Schere, Gynäkologie	<i>Scissors, Gynecological</i>	6	
13-495	Schere, Nase	<i>Scissors, Nasal</i>	5	
13-496	Schere, Neurochirurgie	<i>Scissors, Neurosurgical</i>	6	
13-498	Schere, Orthopädie	<i>Scissors, Orthopedic</i>	6	
13-499	Schere, Pädiatrie	<i>Scissors, Pediatric</i>	6	
13-501	Schere, Rektum	<i>Scissors, Rectal</i>	6	
13-502	Schere, Wundnaht	<i>Scissors, Suture</i>	6	
13-504	Schere, Thorax	<i>Scissors, Thoracic</i>	6	
13-508	Chirurgielöffel	<i>Scoops</i>	6	
13-509	Chirurgielöffel, Gallenstein	<i>Scoops, Gallstone</i>	6	
13-517	Schraubendreher, Knochen	<i>Screwdrivers, Bone</i>	6	
13-630	Schlingeninstrument	<i>Snares</i>	6	
13-642	Untersuchungssonde	<i>Sounds</i>	6	

13-644	Untersuchungssonde, Uterus	<i>Uterine sound</i>	6	
13-645	Spatel	<i>Spatulas</i>	6	
13-649	Spatel, Lunge	<i>Spatulas, Lung</i>	6	
13-650	Spatel, Mikrochirurgie	<i>Spatula, microsurgery</i>	6	
13-662	Spekulum, Ohr	<i>Specula, Ear</i>	5	
13-664	Spekulum, Nase	<i>Specula, Nasal</i>	5	
13-665	Spekulum, rektal	<i>Specula, Rectal</i>	5	
13-666	Spekulum, vaginal	<i>Specula, Vaginal</i>	5	
13-707	Spreizer	<i>Spreaders</i>	6	
13-730	Sterilgutcontainer	<i>Sterilization Containers</i>	1	
13-731	Sterilisationsprozessindikator	<i>Paper label with Indicator</i>	1	
13-755	Stethoskop, mechanisch	<i>Stethoscopes, Mechanical</i>	1	
13-823	Stripper	<i>Strippers</i>	6	
13-827	Stripper, Sehne	<i>Strippers, Tendon</i>	6	
14-066	Zungen-Depressor	<i>Tongue Depressors</i>	5	
14-101	Extensionsbügel	<i>Extension Bow</i>	1	
14-146	Trephine	<i>Trephines</i>	6	
14-154	Trokar	<i>Trocars</i>	6	
14-255	Stimmgabel	<i>Tuning Forks</i>	1	
14-257	Pinzette	<i>Tweezers</i>	6	
15-013	Reinigungsgerät	<i>Cleaners</i>	1	
15-025	Klemme, Schädel	<i>Clamps, Skull</i>	6	
15-076	Laryngoskop, starr	<i>Laryngoscopes, Rigid</i>	5	
15-204	Bohrer, sonstige	<i>Burs, Other</i>	6	
15-206	Kanüle, sonstige	<i>Cannula, other</i>	6	
15-212	Klemme, sonstige	<i>Clamps, Other</i>	6	
15-215	Dilatator, sonstige	<i>Dilatators, Other</i>	5	
15-221	Zange, sonstige	<i>Bending instrument</i>	6	
15-224	Führung, sonstige	<i>Guides, Other</i>	6	
15-225	Haken, sonstige	<i>Hooks, others</i>	6	
15-226	Messer, sonstige	<i>Knives, Other</i>	6	
15-244	Säge, sonstige	<i>Saws, Other</i>	6	
15-245	Schere, sonstige	<i>Scissors, Other</i>	6	
15-246	Schere, Auge, sonstige	<i>Scissors, Eye, Other</i>	5	
15-249	Spatel, sonstige	<i>Spatulas, Other</i>	6	
15-253	Spreizer, sonstige	<i>Spreader, Other</i>	6	
15-256	Spritze, sonstige	<i>Syringe, Other</i>	6	
15-561	Schale	<i>Bowls</i>	1	
15-572	Becher	<i>Cups</i>	1	
15-586	Standgefäß	<i>Jars</i>	1	
15-621	Mikrochirurgieinstrument	<i>Microsurgical Instruments</i>	6	
15-634	Mittelohr-Prüfgerät	<i>Otoscope</i>	5	
15-669	Hohlmeißelzange, Bandscheibe	<i>Rongeurs, Intervertebral Disk</i>	6	
15-670	Zange, Knochen	<i>Forceps, Bone</i>	6	
15-671	Klemme, rektal	<i>Clamps, Rectal</i>	6	
15-672	Zange, Tonsille	<i>Forceps, Tonsil</i>	6	

15-676	Schlingeninstrument, Nase	<i>Snares, Nasal</i>	6	I
15-710	Zange, dental	<i>Forceps, Dental</i>	5	I
15-741	Raspel, Knochen	<i>Rasps, Bone</i>	6	I
15-774	Klinge, Gipsschere	<i>Blades, Cast Cutter</i>	1	I
15-787	Sphinkteroskop	<i>Sphincteroscopes</i>	1	I
15-800	Zange, Dissektion	<i>Forceps, Dissecting</i>	6	I
15-864	Schüssel, Waschen	<i>Basins, Wash</i>	1	I
15-881	Klemme, pädiatrisch	<i>Clamps, Pediatric</i>	6	I
15-882	Klemme, Gefäß	<i>Clamps, Vascular</i>	6	I
16-025	Fremdkörpernadel	<i>Spuds, Eye</i>	6	I
16-209	Zange, ophthalmologisch	<i>Forceps, Ophthalmic</i>	6	I
16-264	Nahtgerät, sonstige	<i>Suture Units, Other</i>	1	I
16-425	Tupferträger, Endoskopie	<i>Cotton carrier, endoscopy</i>	1	I
16-451	Klemme, otologisch	<i>Clamps, Otologic</i>	6	I
16-452	Klemme, Penis	<i>Clamps, Penile</i>	5	I
16-463	Quetschzange	<i>Cartilage crusher</i>	6	I
16-467	Draht-Biegeform	<i>Wire Bending Dies</i>	1	I
16-479	Elevatorium, korneal	<i>Elevators, Corneal</i>	5	I
16-519	Zange, Niere	<i>Forceps, Kidney</i>	6	I
16-520	Schere, Tonsille	<i>Scissors, Tonsil</i>	5	I
16-767	Container	<i>Containers</i>	1	I
16-879	Schaber	<i>Scrapers</i>	6	I
16-985	Gefäß-Tunnelierinstrument	<i>Vessel tunneling instrument</i>	5	I
17-673	Approximator	<i>Approximator</i>	6	I
17-688	Führung, Nähen	<i>Guides, Suturing</i>	6	I
17-761	Bohrinstrument, Orthopädie	<i>Broaches, Orthopedic</i>	6	I
17-899	Kanüle, Auge, Irrigation/Aspiration	<i>Cannulae, Eye, Irrigating/Aspirating</i>	5	I
17-995	Bohrer, orthopädisch	<i>Burs, Orthopedic</i>	6	I

gem. der Richtlinie 93/42/EWG klassifiziert (**Anhang IX**) und gefertigt wurden. Die Produkte sind konform zur EG-Richtlinie 93/42/EWG und dürfen daher mit **CE** gekennzeichnet und von uns in Verkehr gebracht werden. Der Hersteller hat die Technische Dokumentation zusammengestellt. Das Konformitätsbewertungsverfahren unserer Produkte wurde unter eigener Verantwortung nach RL 93/42/EWG, Anhang VII durchgeführt.

have been classified (Annex IX) and produced under consideration of European Medical Device Directive 93/42/EEC. The products are conforming to the European Medical Device Directive 93/42/EEC and may therefore be placed into the market, labelled with **CE**. The manufacturer has compiled the Technical Documentation. The conformity assessment of the devices according to MDD 93/42/EEC, Annex VII has been performed under our sole responsibility.

Eine detaillierte Artikelliste aller Instrumente (**Anhang I**) können wir Ihnen gerne auf Anfrage zukommen lassen.

A detailed article list of all instruments (**Appendix I**) can be sent to you on request.

Dokumentnummer PHA_I-x_A01x01_Konformitätserklärung_Declaration-of-Conformity_v0.2	Erstellt / geändert / Datum KU 2019-02-18	Version v0.2	Geprüft / freigegeb. / Datum – Signum 2019-02-18 KU	Seite von Seite (n) 5 / 6
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Diese Erklärung besitzt eine Gültigkeit bis zum 27.09.2022.

This declaration is valid until the 27.09.2022.

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Wurmlingen, 01.10.2021

Ort/ Datum
Place/Date

Kai-Michael Unger,
Geschäftsführer/General Manager

Dokumentnummer	Erstellt / geändert / Datum	Version	Geprüft / freigegeb. / Datum – Signum	Seite von Seite (n)
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