



EC-CERTIFICATE



(Full quality assurance system)

This is to certify that the company

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Traumatological Implants and Instruments for HF-Surgery, Endoscopes and accessories according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	070894 MR2
Certificate unique ID	170622161
Effective date	2015-05-17
Expiry date	2020-05-16
Frankfurt am Main	2015-05-14

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Strabe 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, info@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

Declaration of Conformity



Konformitätserklärung Declaration of Conformity

Wir,
We,

REDA INSTRUMENTE GMBH

Gänsäcker 34
78532 Tuttlingen / Germany
Tel.: +49 (0)74 62 / 9445-0
Fax: +49 (0)74 62 / 9445-20
e-Mail: info@reda-instrumente.de

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 1, 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, 1/a + 1/b

In refer to our catalogues General Surgical Instruments, Titanium Instruments, Neuro Surgery Instruments,
Sterilization Containers, Endoscopes and Accessories for flexible and rigid Endoscopy

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

Seite 1 von 6

Erstellung	Änderun	Ersatz für	Index:	Datel:	Freigabe:
20.04.2010	19.01.2016		04	Konformitätserklärung_aller REDA öffentlich.doc	

Declaration of Conformity



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

Seite 2 von 6

Erstellung	Änderung	Ersatz für	Index	Datum	Freigabe
20.04.2010	19.01.2016		04		Konformitätserklärung_aller REDA öffentlich.doc

Declaration of Conformity



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

Erstellung:	Änderung:	Ersatz für:	Index:	Datei:	Freigabe:
20.04.2010	19.01.2016		04	Konformitätserklärung_aller REDA öffentlich.doc	

Declaration of Conformity



DE/CA39/833/326	Spritze, Mikro-	syringe micro	CLI	16-878	13929
DE/CA39/833/327	Nasopharyngoskop	Nasopharyngoscope	CLI	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	CLI	17-199	35883
DE/CA39/833/332	Endoskopie Kamera-Adapter	endoscopy camera-adapter	CLI	18-104	36292
DE/CA39/833/333Ä	Rhinoskop	Rhinoscope	KLIIA	13-396	35316
DE/CA39/833/338	Blasenkatheterisierung-/Urinsammelkitt	catheters	CLI	14-292	10685
DE/CA39/833/339Ä	Hvsteroskop	Hvsteroscope rigid	KL II A	12-081	36628
DE/CA39/833/340	Fanqk6rbchen	retrieval basket stones a.foreign bodies	CLI	15-573	35808
DE/CA39/833/342	Urethrotom	Urethrotome	CLI	17-633	17633
DE/CA39/833/347	Kan6le, -sonstige	Cannula, other	KLIIA	15-206	
DE/CA39/833/35	Clip-Wunde	Clip	CLI	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	CLI	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	CLI	15-628	
DE/CA39/833/36	K6urette	Curettes	CLI	11-084	34980
DE/CA39/833/360	Blutdruckmessger6t, aneroid	Blood pressure meter	CLI	16-156	
DE/CA39/833/361	Fixierung	fixation	CLI	13-368	
DE/CA39/833/362	Extraktor, Nagel	Ectractor nail	CLI	12-696	
DE/CA39/833/365	Thorakoskop	Thoracoscope	KL A	14-047	
DE/CA39/833/366	Nephroskop, starr	Nephroscope, rigid	KL A	15-290	15290
DE/CA39/833/367	Starrendoskop	Stiff endoscope	KL A	11-274	
DE/CA39/833/368	Ureterorenoskop	Ureterorenoscope	KL A	17-690	17690
DE/CA39/833/369	Anschl6sse / Adapter	Connectors / Adapters	KL A	11-726	11726
DE/CA39/833/370	Reihbale, orthop6disch	Reamer, orthopedic	KL A	13-297	13297
DE/CA39/833/371	S6ge, Knochen	Saw, bone	KL A	13-449	13449
DE/CA39/833/373	Klammer, Knochen	Clip, bone	KL B	16-103	16103
DE/CA39/833/37	Dermatom	dermatomes	CLI	11-179	11179
DE/CA39/833/40	Dissektionskit	Post Martern Set	CLI	11-289	11289

Erstellun	Änderun	Ersatz für	Index:	Datei:	Freigabe:
20.04.2010	19.01.2016		04	Konformitätserklärung_aller REDA öffentlich.doc	

Declaration of Conformity



DE/CA39/833/44	Handbohrer/ -Dreher	Handdrill / handdriver	KLI	11-345	11345
DE/CA39/833/48	Feile	file	KLI	11-701	11701
DE/CA39/833/53Ä	Messer , Sonstige	knives others	KLI	15-226	35130
DE/CA39/833/55	Säge, Sonstige	Saw other	KLI	15-244	34821
DE/CA39/833/372	Bohrer, orthopädisch	Burs, orthopedic	KL II B	17-995	36249
DE/CA39/833/76	Kopfspiegel	head mirrors	KLI	11-960	31106
DE/CA39/833/78	Klinge Messer	blades knife	KLI	12-234	15558
DE/CA39/833/79	Messerhalter	knife holders	KLI	12-236	12236
DE/CA39/833/87Ä	Larvnoskop	Larvnaoscope	KL II A	12-293	12293
DE/CA39/833/89	Hammer, Knochen	mallets bone	KLI	12-423	32312
DE/CA39/833/90	Nadelhalter	needle holders	KLI	12-726	12726
DE/CA39/833/92	Nadel	needles	KLI	12-729	12729
DE/CA39/833/94	Ophthalmoskop direkt	ophthalmoscope direct	KLI	12-817	12817
DE/CA39/833/95	Ophthalmoskop indirekt	ophthalmoscope	KLI	12-818	12815
DE/CA39/833/97Ä	Otoskop	otoscope	KL IIA	12-849	12849
DE/CA39/833/98	Perkussionshammer	Percussors	KLI	12-986	35235
DE/CA39/833/282	Insufflationsaerät HvsteroskoPie	Insuflator Hvsteroscopy	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 cholangiograohv	KL IIA	16-429	16429
DE/CA39/833/04Ä	Draht Knochen	Wire, bone	KL 118	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	NagelKnochen	Nail, Bone	KL 118	16-078	16078
DE/CA39/833/1 OÄ1	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 118	13-484	35326

klassifiziert gemäß RL 93/42/EWG (M5), Anhang IX, Regel 2, 6, 7 und 11 in Risikoklasse 1, Ila + I Ib
 classified according to MDD 93/42/EEC (M5) annex IX rufe 2, 6, 7 and 11 into risk c/ass I, 1/a + 1/b

Declaration of Conformity



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 **CE0297** 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 CE0297** 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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Thomas Benas
Quality Manager

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

Seite 6 von 6

Erstellung	Änderung	Ersatz für	Index	Datum	Freigabe
20.04.2010	19.01.2016		04		Konformitätserklärung_aller REDA öffentlich.doc

CERTIFICATE



This is to certify that the company

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

has implemented and maintains a **Quality Management System**.

Scope:

Manufacturing and distribution of surgical instruments and medical products, endoscopic instruments and accessories

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2012 + AC : 2012

Certificate registration no.	070894 MP2012
Certificate unique ID	170614201
Effective date	2015-05-17
Expiry date	2018-05-16
Frankfurt am Main	2015-04-17



DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body