



ID-Nr. B-0001/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

General Medicine and ENT Instruments including accessory Allgemeinmedizin und HNO Instrumente inklusive Zubehör

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Otoscope	BETA 100	B-00*.11.52*
Otoscope	BETA 200	B-00*.11.500
Otoscope	K 100	B-00*.11.57* / B-245.10.118
Otoscope	K 180	B-00*.11.550
Otoscope	alpha+	D-00*.80.108
Otoscope	mini 2000	D-001.70.205
Otoscope	mini 3000	D-001.70.2**
Otoscope	mini 2000 F.O.	D-001.70.105
Otoscope	mini 3000 F.O.	D-001.70.1**
Operating Otoscope	-	B-00*.11.492
Reusable Tip	SANALON S black	B-000.11.107-.110
Reusable Tip	SANALON S blue	B-000.11.157-.160
Nasal Speculum	SANALON S	B-000.11.143
Disposable Tip	All-Spec	B-000.11.12*
Reusable Speculum	SANALON S	B-000.11.215-.220
Disposable Speculum	UniSpec	B-000.11.24* / B-000.11.237/8
Straight Laryngeal Mirror	-	B-00*.12.10*
Straight Laryngeal Mirror	mini 2000/3000	D-001.77.10*
Curved Laryngeal Mirror	-	B-00*.12.20*
Tongue Depressor	-	B-00*.12.30*
Tongue Depressor	alpha+/mini 2000	D-00*.74.100
Tongue Depressor	mini 3000	D-001.74.103
Fiberoptics Nasal Illuminator	-	B-00*.12.32*
Fiberoptics Nasal Illuminator	mini 2000	D-001.76.100
Fiberoptics Nasal Illuminator	mini 3000	D-001.76.101
Cliplamp	mini 1000	D-001.73.111
Cliplamp Head	mini 2000	D-001.73.120
Cliplamp Head	mini 3000	D-001.73.130
mini-c Cliplamp Head	mini-c	D-009.73.108
mini-c Cliplamp	mini-c Cliplamp	D-001.73.109
mini-c Cliplamp and Ear Light	-	D-000.73.106/5
Cliplamp	ClipLight	D-001.73.150
Cliplamp	mini 2000	D-001.73.129
Cliplamp	mini 3000	D-001.73.131
Combilamp	mini 2000	D-001.76.119
Combilamp	mini 3000	D-001.76.120
Combilamp without handle	mini 3000	D-001.76.101



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<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Disposable Tongue Blades	-	B-000.11.304
Insufflation Bulb	-	B-000.11.240
Insufflation Bulb	-	D-000.80.102
Spreadable Nasal Speculum	-	B-000.11.231
Universal Speculum	-	B-000.11.239

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2012-01-16 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-01-16

Oliver Heine, BA
- President & CEO -



ID-Nr. C-0001/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Ophthalmic Instruments and accessories

Ophthalmologische Instrumente und Zubehör

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Retinoscope	BETA 200	C-00*.15.3*3
Retinoscope	alpha+	D-00*.83.50*
Retinometer	Lambda 100	C-00*.35.01*
Handlamp	Focalux	C-00*.14.102
Handlamp	Focalux mini 2000	D-001.72.100
Handlamp	Focalux mini 3000	D-001.72.139
Handlamp	alpha+ Focalux	C-00*.72.101
Ophthalmic examination lamp	-	C-00*.14.400
Ophthalmic examination lamp	alpha+	D-00*.81.101
Hand-held Slitlamp	HSL 100	C-00*.14.601
Hand-held Slitlamp	HSL 150	C-00*.14.602
Loupe attachment	HSL 10x	C-00*.14.60*
Hand-held Slitlamp	HSL 100 alpha+	D-00*.81.501
Hand-held Slitlamp	HSL 150 alpha+	D-00*.81.511
Diascleral transilluminator	-	C-00*.17.110
Finoff transilluminator	-	C-00*.17.080
Finoff transilluminator	alpha+	C-00*.83.601
Illuminated magnifier	-	C-00*.14.503
Illuminated magnifier	alpha+	D-00*.82.011
Loupe	5x, 8x	C-000.14.51*
Threshold tonometer	Glaucotest	C-00*.16.201
Binocular loupes / Binocular loupes with i-view (for S-Frame and headband)	G, K, HR, HRP, HR-C	C-000.32.***
Binocular loupes	C 2.3 K	C-000.32.22*
Binocular loupe	C 2.3/340	C-000.32.039
Binocular loupe	C 2.3/450	C-000.32.202
F.O. LoupeLight	F.O. LoupeLight	C-003.32.535
LED LoupeLight	LED LoupeLight	C-008.32.235/541, C-008.32.236/238
Illumination attachment	-	C-004.32.*29
Depressor	-	C-000.17.30*
Klemme/Universal Clip	-	C-000.32.025
Ophthalmoscopy lenses	-	C-000.17.2**
Combi-Frames/Frames	F, FG, P, S	C-000.32.5**
S-Frame	for Binocular loupes	C-00.32.303/300
S-Frame	for Sigma 150	C-000.33.036
S-Guard	for Professional L	C-000.32.403
S-Guard	for Lightweight	C-000.32.401
S-Guard	for 3S LED Headlight	J-000.31.351



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<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
S-Guard	for MD 1000	J-000.31.241
Retrofitting i-View LoupeBracket	for 3SLED Headlight	J-000.31.37*
Retrofitting i-View LoupeBracket	for MD 1000	J-000.31.27*
Conversion set i-View LoupeBracket	3S LED / MD 1000	J-000.31.*80
I-View Loupe Bracket	-	J-000.31.357

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2012-03-19 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-03-19

Oliver Heine, BA
- President & CEO -



ID-Nr. C-0002/01

EC-Declaration of Conformity for medical devices
EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Direct and Indirect Ophthalmoscopes**Direkte und Indirekte Ophthalmoskope**

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Direct Ophthalmoscope	BETA 200	C-00*.30.100
Direct Ophthalmoscope	BETA 200 M2	C-00*.30.102
Direct Ophthalmoscope	BETA 200 S	C-00*.30.120
Direct Ophthalmoscope	K 180	C-00*.30.20*
Direct Ophthalmoscope	mini 3000	D-001.71.1**
Indirect Ophthalmoscope	OMEGA 200	C-00*.33.210
Indirect Ophthalmoscope	SIGMA 150	C-004.33.350, C-004.33.351
Indirect Ophthalmoscope	SIGMA 150 M2	C-004.33.355, C-004.33.356
Indirect Ophthalmoscope	SIGMA 150 K	C-004.33.325, C-004.33.329
Indirect Ophthalmoscope	SIGMA 150 K/M2	C-004.33.335, C-004.33.336
Indirect Ophthalmoscope	SIGMA 150 KC	C-004.33.341, C-004.33.342
Indirect Ophthalmoscope	Video OMEGA 2C	C-004.33.21*
Handheld Indirect Ophthalmoscope		C-00*.33.00*

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2012-08-31 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-08-31



Oliver Heine, BA
- President & CEO -



ID-Nr. C-0003/00

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE OMEGA® 500

(UMDNS-Code: 12-818)

Indirect Ophthalmoscope with LED and XHL illumination und accessory

Indirektes Ophthalmoskope mit LED und XHL Beleuchtung and Zubehör

in the following configurations

<u>Name or Type of device</u>	<u>REF-/Article-/Catalog-Number(s)</u>
OMEGA 500-LED	X-008.87.200, X-095.16.325, X-008.16.325 C-008.33.502 C-008.33.531 to C-008.33.536 C-283.41.302, C-283.41.320 C-283.41.670, C-284.41.670
OMEGA 500-XHL	C-004.33.507 C-004.33.537 to C-004.33.542 C-283.40.300 C-283.40.302, C-283.40.320 C-283.40.670, C-284.40.670

complies with

**Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte**

This declaration of conformity refers to the products marketed since 2012-08-31 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-08-31


Oliver Heine, BA

- President & CEO -



ID-Nr. D-0001/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE mini3000® LED Ophthalmoscope

(UMDNS-Code: 12-817)

Direct Ophthalmoscope with LED illumination and accessory

Direktes Ophthalmoskop mit LED Beleuchtung und Zubehör

in the following configurations

<u>Name or Type of device</u>	<u>REF-/Article-/Catalog-Number</u>
HEINE mini3000® LED Ophthalmoscope	D-008.71.105

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2013-02-08 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2013-02-08

Oliver Heine, BA
- President & CEO -



ID-Nr. D-0002/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE mini3000® LED Dermatoscope

UMDNS-Code: 18-021 | GMDN-Code: -

Epiluminescence microscope (Dermatoscope) with LED illumination and accessory
Epilumineszenz Mikroskop (Dermatoskop) mit LED Beleuchtung und Zubehör

in the following configurations

Name or Type of device

HEINE mini3000® LED Dermatoscope

REF-/Article-/Catalog-Number

D-008.78.106, D-008.78.107, D-008.78.108,
D-008.78.109, D-887.78.021,

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2013-02-08 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2013-02-08

Oliver Heine, BA
- President & CEO -



ID-Nr. D-0003/01

EC-Declaration of Conformity for medical devices
EG-Konformitätserklärung für Medizinprodukte
according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE mini3000® LED F.O. Otoscope

UMDNS-Code: 12-849 | GMDN-Code: -

Fiber optic (F.O.) Otoscope with LED illumination and accessory
Fiber Optik (F.O.) Otokop mit LED Beleuchtung und Zubehör

in the following configurations

Name or Type of device

HEINE mini3000® LED F.O. Otoscope

REF-/Article-/Catalog-Number

D-008.70.106, D-008.70.110, D-008.70.120,
D-885.20.021

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2013-02-08 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2013-02-08

Oliver Heine, BA
- President & CEO -



ID-Nr. E-0001/02

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Proctological Instruments and accessories Proktologische Instrumente und Zubehör

in the following configurations

<u>Name or Type of device</u>	<u>Article-/Catalog-Number</u>
Anoscope/Proctoscope with distal annular illumination	E-003.18.***, E-003.19.*13
Swivel lens	E-003.19.099
Anoscope with annular fiber optics illumination	E-003.19.3**
Instrument head for HEINE UniSpec® tubes	E-003.18.098
HEINE UniSpec® Disposable Tubes	E-003.18.8**
HEINE UniSpec® Disposable Tubes	E-003.19.8**
HEINE UniSpec® Disposable Tubes	E-003.19.9**
Anoscope/Proctoscope with proximal illumination	E-00*.19.1**
Telescope	E-000.18.908
Sponge holder	E-000.18.906
Suction tube	E-000.18.907
Insufflation bulb	E-000.18.105
Hygiene Filter	E-000.18.116
Illumination attachment	E-00*.19.410

complies with

**Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte**

This declaration of conformity refers to the products marketed since 2012-08-31 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-08-31

Oliver Heine, BA
- President & CEO -



ID-Nr. F-0001/02

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

F.O. Laryngoscopes and Handles

F.O. Laryngoskope und -Griffe

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Laryngoscope blades with fiber optics illumination	Classic+ Macintosh	F-000.22.10*
Laryngoscope blades with fiber optics illumination	Classic+ Macintosh 3m	F-000.22.143
Laryngoscope blades with fiber optics illumination	Classic+ Heine Paed	F-000.22.110 / F-000.22.111
Laryngoscope blades with fiber optics illumination	Classic+ Miller	F-000.22.119 / F-000.22.12*
Laryngoscope blades with fiber optics illumination	Classic+ Wis	F-000-22.13*
Laryngoscope blades with fiber optics illumination	SANALON	F-000.22.2**
Laryngoscope blades with fiber optics illumination	FT Flexible Tip	F-000.22.3**
Laryngoscope blades with fiber optics illumination	Modular FO-Laryng.	F-000.22.5**
Laryngoscope blades with fiber optics illumination	XP Mac Disposable	F-000.22.76*
Laryngoscope blades with fiber optics illumination	XP Miller Disposable	F-000.22.77*
Small F.O. laryngoscope battery handle		F-001.22.800
Small F.O. rechargeable laryngoscope handle		F-00*.22.806
F.O. laryngoscope battery handle	F.O. SP	F-001.22.815
Short F.O. laryngoscope battery handle	F.O.	F-001.22.812
Standard F.O. laryngoscope handle	Battery handle F.O.	F-001.22.860
Standard F.O. laryngoscope handle	Rechargeable handle F.O. NiMH	F-001.22.863
Standard F.O. laryngoscope handle	Rechargeable handle F.O. Li-ion L	F-007.22.885
Standard F.O. LED laryngoscope handle	Battery handle F.O. LED	F-008.22.860
Standard F.O. LED laryngoscope handle	Rechargeable handle F.O. LED NiMH	F-008.22.863
Standard F.O. LED laryngoscope handle	Rechargeable handle F.O. LED Li-ion L	F-008.22.891
Angled F.O. laryngoscope handle	F.O. 2,5 V	F-001.22.941
Angled F.O. laryngoscope handle	F.O. 3,5 V (NiMH)	F-002.22.942
Angled F.O. laryngoscope handle	F.O. 3,5 V (Li-ion)	F-007.22.942
Angled F.O. laryngoscope handle	Rechargeable handle F.O. Li-ion L	F-007.22.945
BETA F.O. laryngoscope handle	BETA F.O.	F-001.22.117
BETA F.O. laryngoscope handle	BETA F.O. R	F-002.22.37* / F-007.22.377



ID-Nr. F-0001/02

Name or Type of device

BETA F.O. laryngoscope handle
BETA F.O. laryngoscope handle
BETA F.O. laryngoscope handle
XP handle
Short BETA F.O. laryngoscope handle
(K3Z)
Small F.O. LED Handle

BETA F.O. TR
BETA F.O. NT
Bulb holder
XP handle
NT2 for NT200

Article-/Catalog-Number

F-002.22.38* / F-007.22.385
F-002.22.412 / F-007.22.412
F-00*.22.009
F-000.22.92*
F-002.22.414

F-000.22.851, F-000.22.852,
F-008.22.800,
F-008.22.801, F-000.22.804,
F-008.22.806,
X-000.99.086, X-001.99.306,
X-002.99.495
F-008.22.414, F-008.22.812,
X-001.99.307, X-002.99.495
F-008.22.860, F-008.22.890,
F-001.22.861,
F-000.22.824, F-008.22.863,
F-002.22.867,
X-002.99.382, X-002.99.495

Short F.O. LED Handle

Standard F.O. LED Handle

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).

HEINE OPTOTECHNIK
GmbH & Co KG
Kientalstraße 7, 82211 Herrsching
Tel. +49(0)8152/38-0
Herrsching, 2013-10-28



Bettina Seim
Business Development
HEINE Optotechnik GmbH & Co. KG

ID-Nr. Lary-2013-00

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITYName und Adresse der Firma
name and adress of the firm**HEINE Optotechnik GmbH & Co. KG**
Kientalstrasse 7
D-82211 Herrsching

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

das Medizinprodukt
the medical device**Laryngoscope handle with LED-illumination and accessory**
Laryngoskopgriff mit LED-Beleuchtung und ZubehörBezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl)
(name, type or model, batch or serial number, possibly sources and number of items)
(nom, type ou model, no de lot ou de série, éventuellement sources et nombre d'exemplaires)

Model / Name	Article code	UMDNS	GMDN
HEINE Standard F.O. LED Handle	F-008.22.860, F-001.22.861, F-000.22.824, F-008.22.863, F-002.22.867, F-008.22.890 X-002.99.382, X-002.99.495	12-293	15076

der Klasse / of class / de la classe

INach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of direct. 93/42/EEC / selon de l'annexe IX de la directive 93/42/CEEallen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht, die anwendbar sind
meets all the provisions of the directive 93/42/EEC which apply to itAngewandte harmonisierte Normen,
nationale Normen oder andere
normative Dokumente
Applied harmonised standards,
national Standards or other normative
documents**Safety:****EN 60601-1 :2006 + AC2010****EMC:****EN 60601-1-2:2007**Gemäss den Bestimmungen der
Richtlinie
Following the provisions of directive**Anhang VII, der Richtlinie 93/42/EWG**
Annex VII of directive 93/42/EWGGültigkeit
Validity**Dieses Zertifikat ist gültig bis 2016-02-01.**
This Certificate is valid until 2016-02-01.Herrsching, December 11th, 2013Oliver Heine
CEO(Ort und Datum der Ausstellung)
(Place and date of issue)(Name, Funktion und Unterschrift)
(Name, function and signature)




ID-Nr. J-0001/00

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Light Sources and accessories

Lichtquellen und Zubehör

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Head Light	SL 350	J-004.31.100
Head Light	MD 500 F.O.	J-003.31.21*
Head Light	MD 1000 F.O.	J-003.31.23*
Head Light, LED	MicroLight/S-Frame	J-008.31.290
Head Light, LED	MicroLight/Lightweight Headband	J-008.31.295
Focusing Video-Prism Optics MD 500/1000 F.O.		J-000.31.208
Focusing Video-Prism Optics 3S LED Headlight		J-000.31.320
Clip Lite	UBL 100	J-183.40.100
Examination Light	HL 1200	J-005.27.05*
Examination Light	HL 5000	J-005.27.10*
Universal Fiber Optics Examination Lights	HKL	J-003.27.00*
3S LED-HeadLight	3S LED HeadLight	J-008.31.3**
3S LED HeadLight UNPLUGGED with mPack UNPLUGGED		J-003.31.315
3S LED HeadLight UNPLUGGED with EN50/mPack UNPL.		J-008.31.316

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2011-10-25 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2011-10-25

Oliver Heine, BA

- President & CEO -



ID-Nr. J-008/27

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte according to annex VII of Council Directive 93/42/EEC

We hereby declare under our sole responsibility that the medical device

Examination light with accessory
Untersuchungsleuchte mit Zubehör

HEINE EL 10 LED

of class I

UMDNS-Code: 12-276 | GMDN-Code: 12 276

in the following configurations:

<u>Name or Type of device</u>	<u>REF-/Article-/Catalog-Number</u>
Heine EL10 LED with wall mount	J-008.27.001
Heine EL10 LED with clamp	J-008.27.002
Heine EL10 LED with wheeled stand	J-008.27.003


complies with the

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2013-08-21 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching/2013-08-21


Oliver Heine, BA
- President & CEO -



ID-Nr. K-0001/00

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Dermatological Diagnostic Instruments

Dermatologische Diagnostik Instrumente

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Dermatoscope	DELTA 10	K-00*.34.00*
Dermatoscope	DELTA 20	K-008.34.20*
Dermatoscope	mini 2000	D-001.78.100
Dermatoscope	mini 3000	D-001.78.10*
Dermatoscope	alpha+	D-00*.84.1**
Photo Adaptor for DELTA 20		K-000.34.23*
Video-Dermatoscope		K-002.34.03*
Special Camera	Dermaphot	K-171.00.101
Optics Body	Dermaphot	K-000.34.1**
Adaptor cord		X-000.99.231
SLR Photo Adaptor		K-000.34.18*


complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2011-10-25 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2011-10-25


Oliver Heine, BA
- President & CEO -



ID-Nr. K-0002/02

EC-Declaration of Conformity for medical devices
EG-Konformitätserklärung für Medizinprodukte
according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE DELTA® 20 Plus

UMDNS-Code: 18-021 | GMDN-Code: -

Epiluminescence microscope (Dermatoscope) with optional polarizing filter and accessory
Epilumineszenz Mikroskop (Dermatoskop) mit optionalem Polarisationsfilter und Zubehör

in the following configurations:

<u>Name or Type of device</u>	<u>REF-/Article-/Catalog-Number</u>
HEINE DELTA® 20 Plus Dermatoscope Head	K-008.34.210, K-008.34.212, K-008.34.213, K-008.34.214, K-008.34.215
HEINE DELTA® 20 Plus P Sets for polarisation	K-258.10.118, K-258.20.376, K-258.20.420, K-258.27.376, K-258.29.420
HEINE DELTA® 20 Plus N Sets for immersion	K-257.10.118, K-257.20.376, K-257.20.420, K-257.27.376, K-257.29.420
HEINE DELTA® 20 Plus Sets for polarisation and immersion	K-260.10.118, K-260.20.376, K-259.29.420

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2013-02-08 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2013-02-08

Oliver Heine, BA
- President & CEO -



ID-Nr. M-0001/04

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII in combination with annex V of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE GAMMA Sphygmomanometer

(UMDNS-Code: 16-156) / Class Im

Non-invasive manual aneroid blood pressure meter and accessory

Nicht-invasives manuelles Aneroid Blutdruckmessgerät und Zubehör

in the following configurations

Name or Type of device

Aneroid Sphygmomanometer	GAMMA G7	M-000.09.232, M-000.09.233, M-000.09.554, M-000.09.560
Aneroid Sphygmomanometer	GAMMA G5	M-000.09.230, M-000.09.231, M-000.09.555, M-000.09.561
Aneroid Sphygmomanometer	GAMMA GP	M-000.09.242, M-000.09.243, M-000.09.556, M-000.09.562
Aneroid Sphygmomanometer	GAMMA XXL LF	M-000.09.3**

complies with

**Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte**

This declaration of conformity refers to the products marketed since 2013-10-28 and is valid until a revised declaration of conformity is issued but not longer than 01. Feb. 2016 (expiry date of the Annex V EC-Certificate certificate).

Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt, Germany

CE 0297

HEINE OPTOTECHNIK
Herrsching, 2013-10-28
GmbH & Co. KG
Kientalstraße 7, 82211 Herrsching
Bettina Seim Telefon 0 81 52 / 3 80
Business Development
HEINE Optotechnik GmbH & Co. KG



ID-Nr. M-0002/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE GAMMA Stethoscope

UMDNS-Code: 13-750

in the following configurations

<u>Name or Type of device</u>	<u>Article-/Catalog-Number</u>
HEINE GAMMA 3.1® Pulse Stethoscope	M-000.09.941
HEINE GAMMA 3.2® Arcoustic Stethoscope	M-000.09.942
HEINE GAMMA 3.3® Arcoustic Stethoscope	M-000.09.943
HEINE GAMMA C3® Cardio Stethoscope	M-000.09.944

complies with

**Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte**

This declaration of conformity refers to the products marketed since 2011-11-15 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).

The applied harmonized standards are listed in the manufacturer's technical documentation.



Herrsching, 2011-11-15

Dipl.-Ing. (FH) Jörg Rönnau
- Director Regulatory Affairs -

Oliver Heine, BA
- President and CEO -



ID-Nr. X-0001/00

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Handles and Bulbs

Griffe und Lampen

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Battery handle	mini 2000	D-001.79.009
Battery handle	mini 3000	D-001.79.02*
Battery handle	alpha+	D-001.89.051
Rechargeable handle	alpha+	D-002.89.053
Compact handle	-	X-001.99.105
Compact rechargeable handle	-	X-00*.99.471
Battery handle	BETA	X-001.99.118
Cord handle	BETA	X-000.99.212
Rechargeable handle	BETA NT 3,5 V	X-00*.99.411
Rechargeable handle	BETA R 3,5 V	X-002.99.376
Rechargeable handle	BETA TR 3,5 V	X-002.99.384
Rechargeable handle / bottom insert	BETA L	X-007.99.395 / X-002.99.396
Large battery handle	-	X-001.99.120
Lamp handle	-	X-004.99.60*
Bulbs	XHL	X-00*.88.***
mini-c handle	-	D-001.79.03*


complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2011-10-25 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2011-10-25


Oliver Heine, BA
- President & CEO -



ID-Nr. X-0002/00

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Rechargeable batteries

Ladebatterien

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Rechargeable battery	M2Z	D-001.89.013
Rechargeable battery	S2Z	X-001.99.333
Rechargeable battery	NT 2,5 V	X-001.99.433
Rechargeable battery	S3Z	X-002.99.314
Rechargeable battery	3,5 V NIMH	X-002.99.382
Rechargeable battery	M3Z	X-002.99.106
Rechargeable battery	S5Z	X-004.99.623
Rechargeable battery	HC 6V	X-004.99.624
Rechargeable battery	3,5 V Li-ion	X-007.99.381
Rechargeable battery	NiMH 6V	X-004.99.641
Rechargeable battery	Li-ion for mPack / mPack LL	X-007.99.676
Rechargeable battery	Li-Pol for mPack UNPLUGGED	X-007.99.680
Rechargeable battery	K3Z NIMH	X-002.99.393
Rechargeable battery	mini 2Z	X-001.99.487
Rechargeable battery	3,5 V Li-ion L	X-007.99.383

complies with

**Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte**

This declaration of conformity refers to the products marketed since 2011-10-25 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).

Herrsching, 2011-10-25



Oliver Heine, BA
- President & CEO -



ID-Nr. X-0003/02

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Power Supplies and Chargers

Stromversorgungen und Ladegeräte

CLASS I

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Wall transformer	EN 80	X-095.12.118
Wall transformer, basic unit	EN 90	X-095.12.100
Wall transformer, extension unit	EN 90	X-095.12.125
Table-top transformer	EN 20-1	X-095.17.200
Wall transformer	EN 100	X-095.12.110
Extension unit	EN 100	X-095.12.135
Single-unit	EN 100-1	X-095.12.109
Wall transformer	EN 30	X-095.17.100
Plug-in transformer	E 7	X-095.16.100
Plug-in transformer	E 8	X-095.16.201
Table-top transformer	E 9	X-095.13.200
Charger	NT200	X-000.99.40*
Charger	NT300	X-002.99.495
Charger	miniNT	X-001.99.485
Rechargeable handle	BETA R 3,5 V	X-00*.99.376
Rechargeable handle with transformer	BETA TR 3,5 V	X-00*.99.384
Transformer for rechargeable handle BETA TR 3,5V		X-000.99.308
Plug-in transformer with control unit	EN 15	X-095.16.302
Portable power supply	Accubox II/Accubox II-L	X-004.99.638/645
Plug-in transformer	E 10	X-000.99.328
Plug-in transformer for 3S LED-Headlight		X-095.16.310
Extension cord		X-000.99.207 (SA)
Wall/Table transformer base unit/with mPack/with control unit	EN 50	X-095.17.30*
Control unit for EN 50		X-095.17.305
Transformer with headband rheostat	HC 50	X-095.16.322
Power supply mPack with Li-ion battery	mPack	X-007.99.67*
Power supply mPack with Li-ion battery	mPack LL	X-007.99.66*
HC-Converter	HC-Converter	X-095.17.308
EN 50 UNPLUGGED		X-095.17.310
mPack UNPLUGGED		X-007.99.665



ID-Nr. X-0003/02

complies with

**Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte**

This declaration of conformity refers to the products marketed since 2013-10-28 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching: 2013-10-28
HEINE Optotechnik
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Kientalstr. 7, 82211 Herrsching
Telefon 0 81 52 / 3 80

Bettina Seim
Business Development
HEINE Optotechnik GmbH & Co. KG



ID-Nr. Y-0001/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Light Sources and accessories

Lichtquellen und Zubehör

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Fiber optics projector	HK 4000	Y-096.15.100
Fiber optics projector	HK 6000	Y-096.15.101
Fiber optics projector	HK 7000 D	Y-096.15.124
Fiber optics projector	Xenon 1000	Y-096.15.117
Xenon 1000 bulb		Y-096.15.108
Fiber Optics Cable		Y-003.99.518
F.O. Adaptors		Y-096.12.1**
Wheeled Floor Stand		Y-096.50.00*

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2012-05-23 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-05-23

Oliver Heine, BA
- President & CEO -



ID-Nr. Y-0002/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

Light Sources and accessories

Lichtquellen und Zubehör

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Fiber optics projector	HK 7000	Y-096.15.121

complies with

**Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte**

This declaration of conformity refers to the products marketed since 2012-06-11 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-06-11

Oliver Heine, BA
- President & CEO -