HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

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

Name or Type of device		*Article-/Catalog-Number*
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

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. B-0001/01

Name or Type of device		*Article-/Catalog-Number*
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).

CE

Herrsching, 2012-01-16

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. C-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

Direct and Indirect Ophthalmoscopes

Direkte und Indirekte Ophthalmoskope

in the following configurations

Name or Type of device		*Article-/Catalog-Number*
Direct Ophthalmoscope	BETA 200 Professional	C-00*.30.10*
Direct Ophthalmoscope	BETA 200 S	C-00*.30.120
Direct Ophthalmoscope	Autofoc	C-00*.23.00*
Direct Ophthalmoscope	K 180	C-00*.30.20*
Direct Ophthalmoscope	alpha+ Bl. 1	D-00*.83.102
Direct Ophthalmoscope	alpha+ Bl. 2	D-00*.83.201
Direct Ophthalmoscope	alpha+ Bl. 3	D-00*.83.310
Direct Ophthalmoscope	mini 2000	D-001.71.104
Direct Ophthalmoscope	mini 3000	D-001.71.1**
Indirect Ophthalmoscope	OMEGA 100	C-00*.33.200
Indirect Ophthalmoscope	OMEGA 180	C-00*.33.215
Indirect Ophthalmoscope	OMEGA 200	C-00*.33.210
Indirect Ophthalmoscope	OMEGA 500	C-00*.33.501
Indirect Ophthalmoscope	SIGMA 100	C-004.33.30*
Indirect Ophthalmoscope	SIGMA 150, 150 M2	C-004.33.3**
Indirect Ophthalmoscope	SIGMA 150 KC	C-004.33.341
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 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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. C-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

Ophthalmic Instruments and accessories

Ophthalmogogische Instrumente und Zubehör

in the following configurations

Name or Type of device		*Article-/Catalog-Number*
Retinoscope	BETA 200	C-00*.15.3*3
Retinoscope	alpha+	D-00*.83.50*
Retinometer	Lambda 100	C-00*.35.010
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

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. C-0001/00

Name or Type of device		*Article-/Catalog-Number*
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 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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. E-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

Proctological Instruments and accessories

Proktologische Instrumente und Zubehör

in the following configurations

Name or Type of device	*Article-/Catalog-Number*
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 Unispec tubes	E-003.18.098
Unispec tubes	E-003.18.8**
Unispec tubes	E-003.19.8**
Unispec tubes	E-003.19.9**
Anoscope/Proctoscope with proximal illumination	E-00*.19.1**
Telescope	E-000.18.908
Biopsy forceps	E-000.18.92*
Sponge holder	E-000.18.906
Suction tube	E-000.18.907
Insufflation bulb	E-000.18.105
Anal spreadable speculum	E-000.19.400
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 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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. F-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

F.O. Laryngoscopes and Handles

F.O. Laryngoskope und -Griffe

in the following configurations

Name or Type of device		*Article-/Catalog-Number*
Laryngoscope blades with fiber optics illumination	Macintosh	F-000.22.10*
Laryngoscope blades with fiber optics illumination	Macintosh 3m	F-000.22.143
Laryngoscope blades with fiber optics illumination	Heine Paed	F-000.22.11*
Laryngoscope blades with fiber optics illumination	Miller	F-000.22.12*
Laryngoscope blades with fiber optics illumination	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

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. F-0001/00

Name or Type of device		*Article-/Catalog-Number*
BETA F.O. laryngoscope handle	BETA F.O. TR	F-002.22.38* / F-007.22.385
BETA F.O. laryngoscope handle	BETA F.O. NT	F-002.22.412 / F-007.22.412
BETA F.O. laryngoscope handle	Bulb holder	F-00*.22.009
XP handle	XP handle	F-000.22.92*
Short BETA F.O. laryngoscope handle (K3Z)	NT2 for NT200	F-002.22.414

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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

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

Name or Type of device		*Article-/Catalog-Number*
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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

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

Name or Type of device		*Article-/Catalog-Number*
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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. M-0001/ 02

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)

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
Aneroid Sphygmomanometer	GAMMA G5
Aneroid Sphygmomanometer	GAMMA GP
Aneroid Sphygmomanometer	GAMMA GST
Aneroid Sphygmomanometer	GAMMA XXL LF

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 27. Jan. 2012 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

Herrsching, 27. Jan. 2012

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

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

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

Name or Type of device	*Article-/Catalog-Number*
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.

CE

Herrsching, 2011-11-15

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

Oliver Heine, BA
- President and CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

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

Name or Type of device		*Article-/Catalog-Number*
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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. Y-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

Name or Type of device		*Article-/Catalog-Number*
Fiber optics projector	HK 4000	Y-096.15.100
Fiber optics projector	HK 6000	Y-096.15.101
Fiber optics projector	HK 7000	Y-096.15.121
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 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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

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

Name or Type of device		*Article-/Catalog-Number*
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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. X-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

Power Supplies and Chargers

Stromversorgungen und Ladegeräte

in the following configurations

Name or Type of device		*Article-/Catalog-Number*
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-002.99.376
Rechargeable handle with transformer	BETA TR 3,5 V	X-002.99.384
Transformer for rechargaeble 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

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

ID-Nr. X-0003/00

Name or Type of device
mPack UNPLUGGED

Article-/Catalog-Number
X-007.99.665

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).

CE

Herrsching, 2011-10-25

Oliver Heine, BA
- President & CEO -

HRA 52 039 München - Heine Optotechnik Verwaltungs-GmbH, Herrsching, HRB 45192 München
Geschäftsführer: Dipl.-Kfm. Helmut M. Heine, Oliver Heine (BA) – WEEE-Reg.Nr.: DE 87119271