Autorizzazione a contrarre e contestuale affidamento diretto, ai sensi dell'art. 50, comma 1, lett. b), del D.Lgs. 36/2023, del servizio di fornitura di strumentazione diagnostica oftalmologica destinata alle Case della Comunità PNRR-ASL n 1di Sassari. CIG: BC87CCF410.

acquistinretepa

SISTEMI DI E-PROCUREMENT

DOCUMENTO DI OFFERTA ECONOMICA

NUMERO DI RDO: 6485353

Offerta Economica relativa a

Descrizione Autorizzazione a contrarre e contestuale affidamento diretto, ai sensi dell'art. 50, comma 1, lett b del D.Lgs. 36/2023, della fornitura di strumentazione diagnostica oftalmologica per le Case della Comunità PNRR-ASL n 1 di Sassari

RdO nr. 6485353

Numero lotto 0

Amministrazione titolare del procedimento

Ente acquirente	AZIENDA SOCIO SANITARIA LOCALE - 1 - DI SASSARI		
Ufficio	S.C. FLUSSI INFORMATIVI E TECNOLOGIE SANITARIE		
Codice fiscale	02884000908	**Codice univoco ufficio**	Non presente
Indirizzo sede	Via enrico costa 57		
Città	Sassari		
Recapito telefonico	+390792005055		
Email	GIUSEPPINA.DURGALI@ASLSASSARI.IT		
Punto ordinante	Giuseppina Durgali		

Concorrente

Forma di partecipazione

Singolo operatore economico

Ragione sociale/Denominazione

SURGITEK Srl

Partita IVA

01526340920

Tipologia societaria

Società a responsabilità limitata (SRL)

Oggetto dell'Offerta

Formulazione dell'Offerta Economica = Valore economico (Euro)

DATA DI GENERAZIONE DOCUMENTO: 23/07/2026

Nome	Valore
Valore offerto	108740,00

Il Concorrente, nell'accettare tutte le condizioni specificate nella documentazione del procedimento, altresì dichiara:

- che la presente offerta è irrevocabile ed impegnativa sino al termine di conclusione del procedimento, così come previsto nella lex specialis;
- che la presente offerta non vincolerà in alcun modo la Stazione Appaltante/Ente Committente;
- di aver preso visione ed incondizionata accettazione delle clausole e condizioni riportate nel Capitolato Tecnico e nella documentazione di Gara, nonché di quanto contenuto nel Capitolato d'oneri/Disciplinare di gara e, comunque, di aver preso cognizione di tutte le circostanze generali e speciali che possono interessare l'esecuzione di tutte le prestazioni oggetto del Contratto e che di tali circostanze ha tenuto conto nella determinazione dei prezzi richiesti e offerti, ritenuti remunerativi;
- di non eccepire, durante l'esecuzione del Contratto, la mancata conoscenza di condizioni o la sopravvenienza di elementi non valutati o non considerati, salvo che tali elementi si configurino come cause di forza maggiore contemplate dal codice civile e non escluse da altre norme di legge e/o dalla documentazione di gara;
- che i prezzi/sconti offerti sono omnicomprensivi di quanto previsto negli atti di gara;
- che i termini stabiliti nel Contratto e/o nel Capitolato Tecnico relativi ai tempi di esecuzione delle prestazioni sono da considerarsi a tutti gli effetti termini essenziali ai sensi e per gli effetti dell'articolo 1457 cod. civ.;
- che il Capitolato Tecnico, così come gli altri atti di gara, ivi compreso quanto stabilito relativamente alle modalità di esecuzione contrattuali, costituiranno parte integrante e sostanziale del contratto che verrà stipulato con la stazione appaltante/ente committente.

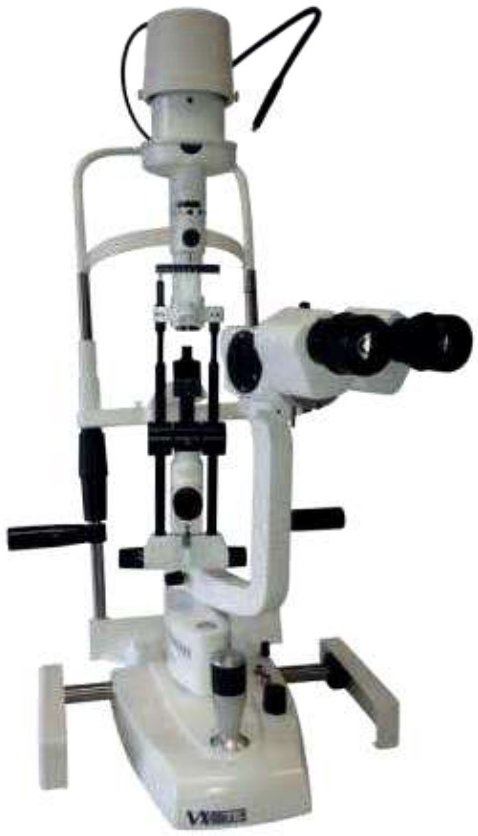
ATTENZIONE: QUESTO DOCUMENTO NON HA VALORE SE PRIVO DELLA SOTTOSCRIZIONE A MEZZO FIRMA DIGITALE

NUMERO DI RDO: 6485353

SISTEMI DI E-PROCUREMENT

DATA DI GENERAZIONE DOCUMENTO: 23/07/2026

VX75 5x fotografica



Lampada a fessura a colonna: una tecnologia comprovata con illuminazione a led

La nostra gamma di lampade a fessura garantisce la sicurezza d'uso grazie ad un'ottica e una tecnica di illuminazione affidabili.

Proiettore a fessura di punta

> Immagini a fessura di eccellente qualità grazie a condizioni di apertura e luce regolate con cura
> Lunghezze di fessura variabili da 1 a 12 mm

Uno stereomicroscopio convincente

> Permette di osservare l'oggetto ad una comoda distanza e con un angolo stereoscopico favorevole.
> Permette di scegliere fra vari dispositivi di ingrandimento con varie graduazioni d'ingrandimento.
> Permette l'adattamento alle abitudini visive mediante diversi tubi.
> Permette di visualizzare dettagli dell'immagine che rendono superflua una continua regolazione della lampada a fessura.

Comfort di utilizzo grazie ad accorgimenti ergonomici

> Comoda distanza operativa
> Slitta a croce, comando con una mano sola
> Il lavoro è facilitato grazie alla corsa ridotta e alla disposizione ergonomica che contraddistinguono il sistema di regolazione della fessura, i filtri, le scale e gli arresti
> Modello adatto sia per i destrimani che per i mancini

OPZIONI

- Tonometro T900 VS.05.006
- Trasformatore obbligatorio per installazione su tavolo a sollevamento elettrico XA.07.030

VX 75
Slit Lamp fotografica

SPECIFICHE TECNICHE

Massima lunghezza della fessura	12 mm
Massima intensità luminosa	248000 Lx
Larghezza fessura	0-12 mm
Lunghezza fessura	da 1 a 12 mm
Punto di Tyndall	< 0,2mm
Rotazione fessura	± 90° in continuo sullo schema Tabo
Sorgente luminosa	WHITE LED
Distanza di lavoro (occhio - prisma)	80 mm
Distanza interpupillare	da 50 a 80 mm

RIF	XS.05.027	Convergenti 5 ingrandimenti
Microscopio	"Ingrandimento/Campo visivo ..... 6x; 10x; 16x; 25x; 40x con 5 ingrandimenti e oculare 12,5x"	
	Angolo stereo ..... 6°	
	Regolazione distanza OD/OS ..... 50 - 80 mm	
Caratteristiche elettriche	Alimentazione della lampada a fessura ..... ~12V CA; ~15V DC	
	Voltaggio luce di fissazione ..... 12 V~	
	Frequenza ..... 50 -60 Hz	
	Fusibile ..... "100-120V CA -- 1A	
	..... 230-240V CA -- 0,5A"	

Dichiarazione di conformità a direttiva CEE
Statement of compliance with EEC Directive

CE 1

La C.S.O. srl - Costruzione Strumenti Oftalmici con sede e stabilimento in *with headquarters at* Via Degli Stagnacci 12/E - Cap 50018 - Badia a Settimo -Scandicci - Firenze - Italia

Fabbricante responsabile *manufacturers*
Famiglia / Family**: Lampade a Fessura / Slit Lamp**

Modello - *Model*: **SL990; SL980; SL950; SL930; SL1000; SL1800; SL9900 SL9800**

- **In tutte le configurazioni inclusa la versione ELite / *In all the configuration included SL9900 Elite version***
- **con separatore digitale e software di gestione Phoenix (se applicabile) / with digital beam splitter and Phoenix SW (if applicable)**

nella persona dei suoi legali rappresentanti Veronica Mura,
in the person of its legal representative Veronica Mura

DICHIARA
WHO ASSUMES
sotto la propria personale responsabilità
full personal liability for the following, hereby certifies

che il prodotto sopra menzionato è progettato e costruito in conformità alle prescrizioni contenute nella:
Direttiva 93/42/CEE "Dispositivi Medici" del 14/06/1993 come emendato dalla direttiva 2007/47/CE

– Esso è di **classe I**, (allegato IX della direttiva citata regola 1).
– E' stato immesso in commercio con la marcatura CE ,
–

I rapporti completi di test eseguiti su un esemplare di serie e il resto della documentazione tecnica, e di assicurazione qualità (prevista dall'allegato VII della direttiva citata) sono conservati nell'archivio della CSO srl.

that the aforementioned product is designed and built in compliance with the requirements contained in:
Directive 93/42/EEC "medical devices" dated 14/06/1993, as emended by 2007/47/CE directive
using the following norms:

– *"*
– *The product is **class I**, as the cited Directive (rule 1)*
– *It is put in market with mark* CE ,
–

The complete test reports performed on one model taken from the series production, and the rest of the technical, production and quality assurance documents (as called for in attachment VII to cited directive) are on file in the CSO srl company archives.

Scandicci 10/07/2019

I legali rappresentanti della CSO Srl

CE_FT002_rev01

VX 36

Misura il potere delle lenti in modo semplice ed immediato

VISIONIX

INNOVATION TO UNLOCK YOUR POTENTIAL

vx 36

Frontifocometro automatico con misurazione della trasmissione della luce blu

Consente di misurare il potere delle lenti in modo semplice ed immediato. La nuova generazione di frontifocometri consente di misurare la percentuale di assorbimento della luce blu offrendo un layout grafico intuitivo per eseguire le misurazioni in modo semplice e immediato.

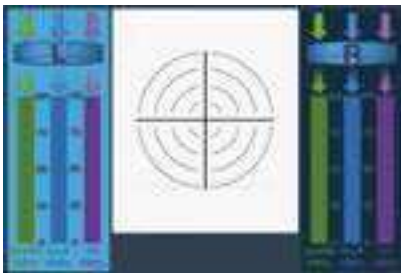
Semplice e automatico

VX 36 offre le seguenti funzioni:

1

Modalità Lenti

- Questa modalità consente di misurare il potere delle lenti, sia su montatura, sia per lenti singole.



2

Modalità UV per la trasmittanza della luce blu

- Questa modalità consente di misurare la trasmittanza della luce nelle porzioni blu (HEV) e ultravioletta dello spettro di luce.

.

3

Visualizzazione delle lenti

- Il modello in scala 1:1 aiuta a scegliere la lente delle dimensioni giuste con la corretta PD.

4

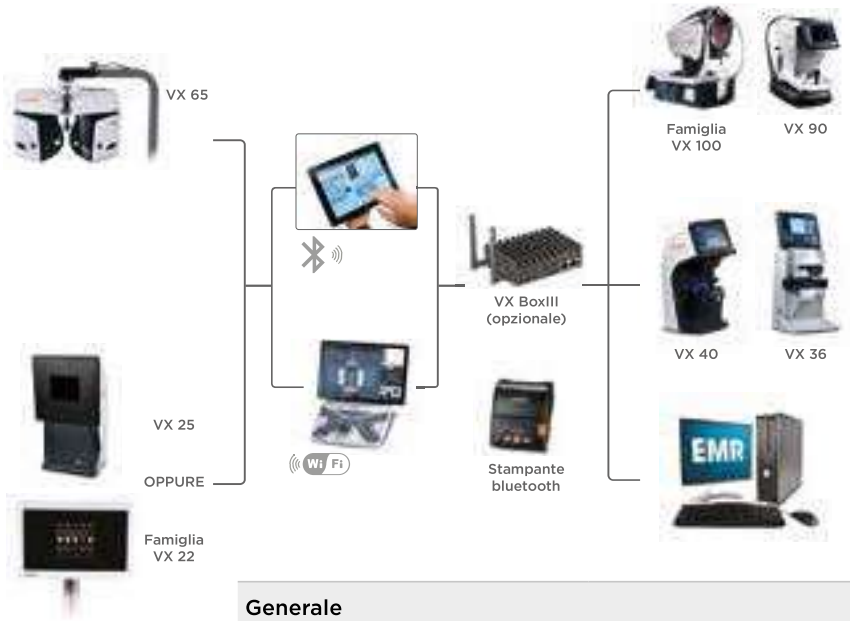
Integrazione flessibile

- La connessione a dispositivi compatibili è possibile tramite WIFI o porta seriale.

Interfacciamento con tutta la gamma dei prodotti Visionix e con le EMR*

- Interfaccia completa per la gestione dati da dispositivi esterni (EMR/ARK)
- Importazione dati wireless da altri dispositivi (come AR/K e frontifocometri) tramite VXbox
- Esportazione dei dati refrattivi nel sistema EMR con il semplice tocco di un pulsante

*Cartelle cliniche elettroniche



Generale	
Visualizzazione dei dati di misurazione	800 x 480 Schermo touch TFT 7 “
Stampante	Stampante termica da 57 mm
Fonte di alimentazione / consumo	110V-240V AC, 50/60 Hz
Potenza nominale Marcatore	35VA 3 punte auto - inchiostranti
Intervallo di misurazione	
Intervallo di misurazione della sfera	-25.00 D a +25.00 D
Intervallo di misurazione del cilindro	0D a +/- 10D
Intervallo di misurazione dell’asse del cilindro	0° a 180° (Passi: 1°)
Intervallo di misurazione ADD	0D a 10D (Passi: 0.01D/0.06D/0.12D/0.25D)
Intervallo di misurazione del prisma	0 a 20△
Modalità di misurazione	Coordinate cartesiane Coordinate polari P-B Passi: 0.01△
Diametro delle lenti misurabili	ϕ10mm a ϕ90 mm
Intervallo di misurazione PD	42mm a 82mm
Intervallo di misurazione PH	8mm a 45mm
Misurazione di osservazione	Trasmissione UV
Lunghezza d’onda per la misurazione della potenza del vertice	525 nm
Lunghezza d’onda per la misurazione UV-A	365 nm

Dimensioni:

LARGHEZZA	233 mm
LUNGHEZZA	203 mm
ALTEZZA	471 mm
PESO	4.5 kg

Normative:
Il VX 36 è conforme alle seguenti direttive:
Direttiva EMC: 2014/30/UE
Direttiva Bassa Tensione: 2014/35/UE
Direttiva ROHS2: 2011/65/UE

CE

VISIONIX

INNOVATION TO UNLOCK YOUR POTENTIAL

VISIONIX ITALIA SRL
Via dei Pioppi 18 - 20024 Garbagnate M.se -Mi-
Tel 02.55413251/221 - Fax 02.55413243
contact-it@visionix.com

www.visionix.com

DECLARATION DE CONFORMITE CE

EC DECLARATION OF CONFORMITY

VX36
frontofocomètre/autolensmeter

Nous soussignés, déclarons sous notre responsabilité que le dispositif spécifié ci-dessus est conforme aux exigences essentielles des Directives et normes suivantes :

We the undersigned, hereby declare that the device specified below is in conformity with the requirements of the following directives and standards:

Directives:
- 2014/35/EU
- 2014/30/EU
- 2011/65/EU

Normes / Standards:
- EN61010-1 :2010
- EN61000-6-3 :2007+A1 :2011
- EN61000-3-2 :2014
- EN61000-3-3 :2013
- EN61000-6-1 :2007

Fabricant / Manufacturer: **LUNEAU SAS**
1 avenue de Malaguet
28360 Prunay le Gillon
FRANCE

Prunay le Gillon,
21/11/2017

.....

Isabelle Durand
Directeur Qualité
Quality Manager

Polyoftalmica
strumenti per l'oftalmologia

via A. B. Sabin, 5/C 43100 Pilastrello (PR)
tel. +39 0521 642126 fax +39 0521 643941
e-mail: info@polynew.it

Heine

BETA 200

Retinoscopio/Schiascopio della linea Heine modello BETA 200. Il retinoscopio BETA 200 con ParaStop ed ottica antirifl essi, produce un'immagine eccezionalmente chiara del riflesso retinico ed una facile individuazione del punto di neutralizzazione.

Precisa selezione di un fascio di raggi paralleli

- ParaStop. Per una selezione istantanea e precisa di un fascio di raggi di luce paralleli.
- Forma ergonomica. Si adatta alla cavità orbitale proteggendo da luci laterali l´occhio dell´osservatore.
- Tecnologia alogena XHL Xenon. Luce bianca e chiara: nitido riflesso retinico.
- Uno strumento sia per retinoscopia a fessura che a spot. É sufficiente cambiare la lampadina.
- Elemento di comando in metallo. Di alta qualità e lunga durata.
- Un solo comando per convergenza e rotazione. Di facile utilizzo con il solo pollice.
- Tenuta ermetica. Elimina la manutenzione.
- Filtro polarizzatore integrato. Elimina riflessi interni e luci parassite.
- Filtro arancione applicabile alla lampadina (optional). Riduce irritazioni al paziente senza compromettere i riflessi del fondo oculare.
- Distanziatore rimovibile. Maggior comfort e controllo durante la visita.
- Fessure per cartoncini di fissazione (optional). Per una retinoscopia dinamica.

Lo strumento è in offerta in varie versioni/composizioni:

- Solo testina senza manico. La testina è ordinabile sia per manico a pile 2,5V che per manico a batterie 3,5V.
- Con manico a batterie ricaricabili 3,5V.
- Con manico a pile 2,5V.
- Set che include strumento con manico a pile 2,5V in astuccio rigido con lampadina di ricambio.
- Set che include strumento con manico a batterie ricaricabili 3,5V in astuccio rigido. La ricarica della batteria può avvenire: con manico per presa diretta a rete, trasformatore a rete, caricatore NT-300 da tavolo.
- Il Set può anche includere la testina dell' Oftalmoscopio Beta 200 oppure Beta 200S sempre in astuccio rigido e con possibilità di scelta del manico.

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-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

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*.35.01*
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

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-0001/01

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 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).

CE

Herrsching, 2012-03-19

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-0002/01

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

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

CE

Herrsching, 2012-08-31

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-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

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

CE

Herrsching, 2012-08-31

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. 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

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

CE

Herrsching, 2013-02-08

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. 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	*REF-/Article-/Catalog-Number*
HEINE mini3000® LED Dermatoscope	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).

CE

Herrsching, 2013-02-08

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. 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.) Otoskop mit LED Beleuchtung und Zubehör

in the following configurations

Name or Type of device	*REF-/Article-/Catalog-Number*
HEINE mini3000® LED F.O. Otoscope	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).

CE

Herrsching, 2013-02-08

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-0001/02

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

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 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).

CE

Herrsching, 2012-08-31

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-0001/02

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

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

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-0001/02

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
Small F.O. LED Handle		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
Short F.O. LED Handle		F-008.22.414, F-008.22.812, X-001.99.307, X-002.99.495
Standard F.O. LED Handle		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

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).

CE

HEINE OPTOTECHNIK GmbH & Co KG Kientalstraße 7, 82211 Herrsching Tel. 08152/38-0

Herrsching, 2013-10-28

Bettina Seim
Business Development
HEINE Optotechnik GmbH & Co. KG

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

ID-Nr. Lary-2013-00

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name 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 Zubehör

Bezeichnung, 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

I

Nach 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/CEE

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht, die anwendbar sind
meets all the provisions of the directive 93/42/EEC which apply to it

Angewandte 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/EWG

Gültigkeit
Validity

Dieses Zertifikat ist gültig bis 2016-02-01.
This Certificate is valid until 2016-02-01.

Herrsching, December 11th , 2013

(Ort und Datum der Ausstellung)
(Place and date of issue)

Oliver Heine
CEO
(Name, Funktion und Unterschrift)
(Name, function and signature)

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. 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:

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

CE

Herrsching, 2013-08-21

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. 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:

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

CE

Herrsching, 2013-02-08

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-0001/04

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

Herrsching, 2013-10-28

HEINE OPTOTECHNIK
GmbH & Co KG
Kientalstraße 7, 82211 Herrsching
Telefon 0 81 52 / 3 80

Bettina Seim
Business Development
HEINE Optotechnik GmbH & Co. KG

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. 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-0003/02

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

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-00*.99.376
Rechargeable handle with transformer	BETA TR 3,5 V	X-00*.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
mPack UNPLUGGED		X-007.99.665

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-0003/02

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).

CE

Herrsching, 2013-10-28

HEINE Optotechnik GmbH & Co KG
Kientalstr. 7, 82211 Herrsching
Telefon 0 81 52 / 3 80

Bettina Selm
Business Development
HEINE Optotechnik GmbH & Co. KG

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-0001/01

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

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 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).

CE

Herrsching, 2012-05-23

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-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

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

CE

Herrsching, 2012-06-11

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