

**Certificate of Conformity**

ENT Instruments and accessories (replaces issue of 24.07.2003)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.
Otoscopes	BETA 100	B-0*.11.205
	BETA 200	B-0*.11.500
	K 100	B-0*.11.204
	K 180	B-0*.11.550
	alpha+	D-0*.80.108
	mini 2000	D-01.70.205
	mini 3000	D-01.70.2**
	mini 2000 F.O.	D-01.70.105
	mini 3000 F.O.	D-01.70.1**
Operating Otoscope	-	B-0*.11.492
Reusable Tips	SANALON S black	B-00.11.107-.110
	SANALON S blue	B-00.11.157-.160
Nasal Specula	SANALON S	B-00.11.143
Disposable Tips	All-Spec	B-00.11.12*
Reusable Specula	SANALON S	B-00.11.215-.220
Disposable Specula	UniSpec	B-00.11.24*
Straight Laryngeal Mirror	-	B-0*.12.10*
Straight Laryngeal Mirror	mini 2000/3000	D-01.77.10*
Curved Laryngeal Mirror	-	B-0*.12.20*
Tongue Depressor	-	B-0*.12.30*
Tongue Depressor	alpha+/mini 2000	D-0*.74.100
	mini 3000	D-01.74.103
Fiberoptics Nasal Illuminator	-	B-0*.12.32*
Fiberoptics Nasal Illuminator	mini 2000	D-01.76.100
	mini 3000	D-01.76.101
Cliplamp	mini 1000	D-01.73.111
Cliplamp Head	mini 2000	D-01.73.120
	mini 3000	D-01.73.130
mini-c Cliplamp Head	mini-C	D-09.73.108
mini-c Cliplamp	mini-C Cliplamp	D-01.73.109
Cliplamp	ClipLight	D-01.73.150
Cliplamp	mini 2000	D-01.73.129
Cliplamp	mini 3000	D-01.73.131
Disposable Tongue Blades	-	B-00.11.304
Insufflation Bulb	-	B-00.11.240
Insufflation Bulb	-	D-00.80.102
Spreadable Nasal Speculum	-	B-00.11.231
Universal Speculum	-	B-00.11.239

Certificate of Conformity ENT Instruments and accessories

Tip-adapter	-	B-00.11.306
Tip-dispenser	All-Spec	B-00.11.148
Specula-dispenser	UniSpec	B-00.11.146

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in according to appendix IX, roul 10: Class IIa. Conformity is assured according to the guidelines set out in appendix VII.

Conformity is assessed according to appendix II.3.

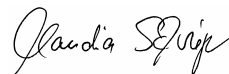
Thermometer EN 100T	EN 100T	B-00.10.009
IR-Thermometer	-	B-00.10.008

Herrsching, 20. Sept. 2006

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Dirk Schade
Director of Research and Development



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Claudia Schwieger
Director of Quality Management

**Certificate of Conformity**
Ophthalmoscopes (replaces issue of 18.7.2005)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description

Direct Ophthalmoscopes

TypeBETA 200 Professional
BETA 200 S
Autofoc
K 180
alpha+ Bl. 1
alpha+ Bl. 2
alpha+ Bl. 3
mini 2000
mini 3000**Cat. No.**C-0*.30.10*
C-0*.30.120
C-0*.23.00*
C-0*.30.20*
D-0*.83.102
D-0*.83.201
D-0*.83.310
D-01.71.104
D-01.71.1**

Indirect Ophthalmoscopes

OMEGA 100
OMEGA 180
OMEGA 200
OMEGA 500
SIGMA 100
SIGMA 150, 150 M2
SIGMA 150 KC
Video OMEGA 2CC-0*.33.200
C-0*.33.215
C-0*.33.210
C-0*.33.501
C-04.33.30*
C-04.33.3**
C-04.33.341
C-04.33.21*
C-0*.33.00*

Handheld indirect Ophthalmoscope

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Herrsching, 20. Sept. 2006

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Dirk Schade

Director of Research and Development

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Claudia Schwieger

Director of Quality Management

**Certificate of Conformity**

Ophthalmic Instruments and accessories (replaces issue of 20.Sept. 2006)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.
Retinoscope	BETA 200	C-0*.15.3*3
	alpha+	D-0*.83.50*
Retinometer	Lambda 100	C-0*.35.010
Handlamp	Focalux	C-0*.14.102
	Focalux mini 2000	C-01.72.100
	Focalux mini 3000	C-01.72.139
	alpha+ Focalux	C-0*.72.101
Ophthalmic examination lamp	-	C-0*.14.400
	alpha+	D-0*.81.101
Hand-held Slitlamp	HSL 100	C-0*.14.601
Hand-held Slitlamp	HSL 150	C-0*.14.602
Loupe attachment	HSL 10x	C-0*.14.60*
Hand-held Slitlamp	HSL 100 alpha+	D-0*.81.501
Hand-held Slitlamp	HSL 150 alpha+	D-0*.81.511
Diascleral transilluminator	-	C-0*.17.110
Finoff transilluminator	-	C-0*.17.080
	alpha+	C-0*.83.601
Illuminated magnifier	-	C-0*.14.503
	alpha+	D-0*.82.011
Loupe	5x, 8x	C-00.14.51*
Threshold tonometer	Glaucotest	C-0*.16.201
Binocular loupes	G, K, HR, HRP, HR-C	C-00.32.***
Binocular loupes	C 2.3 K	C-00.32.22*
Binocular loupe	C 2.3/340	C-00.32.039
Binocular loupe	C 2.3/450	C-00.32.202
F.O. LoupeLight	F.O. LoupeLight	C-03.32.535
LED LoupeLight	LED LoupeLight	C-08.32.235/541
Illumination attachment	-	C-04.32.*29
Depressor	-	C-00.17.30*
Klemme/Universal Clip	-	C-00.32.025
Ophthalmoscopy lenses	-	C-00.17.2**
Combi-Frames/Frames	F, FG, P, S	C-00.32.5**
S-Frame for Binocular loupes/Sigma 150	S-Frame	C-00.32.301/33.036
S-Guard	for Professional L	J-00.32.403
	for Lightweight	C-00.32.401
	for 3S LED Headlight	J-00.31.351
	for MD 1000	J-00.31.241
	for 3SLED Headlight	J-00.31.37*
	for MD 1000	J-00.31.27*
	3S LED / MD 1000	J-00.31.*80
		J-00.31.357

Herrsching, 1. Oct. 2007

ppa.

Dirk Schade
Director of Research and DevelopmentClaudia Schwiieger
Director of Quality Management



Kientalstr. 7
82211 Herrsching



Certificate of Conformity

Proctological instruments and accessories (replaces issue of 24.07.2003)


We certify that the following products conform to the specifications of the Medical Device Directive 93/42 EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.
Anoscope/Proctoscope with distal annular illumination		E-03.18.** E-03.19.*13
Swivel lens		E-03.19.099
Anoscope with annular fiber optics illumination -		E-03.19.3** E-03.18.098
Instrument head for Unispec tubes		
Unispec tubes	-	E-03.18.8** E-03.19.8** E-03.19.9** E-0*.19.1**
Anoscope/Proctoscope with proximal illumination	-	E-00.18.908
Telescope	-	E-00.18.92*
Biopsy forceps	-	E-00.18.906
Sponge holder	-	E-00.18.907
Suction tube	-	E-00.18.105
Insufflation bulb	-	E-00.19.400
Anal spreadable speculum	-	E-0*.19.410
Illumination attachment	-	

Applied Standards

EN 1041:1998, EN 1441:1998, ISO 14971-1:1998, IEC 60601-1:1996

Herrsching, 20.11.2004

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Dirk Schade
Director of Research and Development



ppa.
Dieter Fottner
Technical Production Manager

**Certificate of Conformity**

F.O. Laryngoscopes and handles (replaces issue of 4. May 2006)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42 EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.	
Laryngoscope blades with fiber optics illumination	MacIntosh	F-00.22.10*	
	MacIntosh 3m	F-00.22.143	
	Heine Paed	F-00.22.11*	
	Miller	F-00.22.12*	
	Wis	F-00-22.13*	
	SP	F-00.22.2**	
	FT Flexible Tip	F-00.22.3**	
	Modular FO-Laryng.	F-00.22.5**	
	XP Mac sterile	F-00.22.74*	
	XP Miller sterile	F-00.22.75*	
	XP Mac non-sterile	F-00.22.76*	
	XP Miller non-sterile	F-00.22.77*	
	Small F.O. laryngoscope battery handle		F-01.22.800
	Small F.O. rechargeable laryngoscope handle		F-0*.22.806
F.O. laryngoscope battery handle	F.O. SP	F-01.22.815	
Short F.O. laryngoscope battery handle	F.O.	F-01.22.812	
F.O. laryngoscope battery handle	F.O.	F-01.22.860	
F.O. rechargeable laryngoscope handle	F.O. NT 3,5 V	F-02.22.863	
Angled F.O. laryngoscope handle	F941/F942	F-0*.22.94*	
BETA F.O. laryngoscope handle	BETA F.O.	F-01.22.117	
	BETA F.O. R	F-02.22.37*	
	BETA F.O. TR	F-02.22.38*	
	BETA F.O. NT	F-02.22.4**	
Bulb holder for BETA F.O. laryngoscope handles	-	F-0*.22.009	
XP handle	XP handle	F-00.22.92*	
Short BETA F.O. laryngoscope battery handle (K3Z)	NT2 for NT200	F-02.22.414	

Herrsching, 1. Oct. 2007

ppa.

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Dirk Schade
Director of Research and Development.....
Claudia Schwieger
Director of Quality Management



Kientalstr. 7
82211 Herrsching



Certificate of Conformity

Gynaecological Diagnostic Instruments (replaces issue of 7.2.2000)


We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.
Amnioscope Tube 12Ø	-	H-00.28.*12
Amnioscope Tube 16Ø	-	H-00.28.*16
Amnioscope Tube 20Ø	-	H-00.28.*20
Amnioscope Illumination Head with bulb	-	H-02.28.001
Amnioscope Illumination Head with F.O	-	H-03.28.100
Illumination Head for Small Vaginal Speculum	.	G-0*.21.301
Small Vaginal Speculum	-	G-00.21.360


Applied Standards

EN 1041:1998, EN 1441:1998, ISO 14971-1:1998, IEC 60601-1:1996

Herrsching, den 24.07.2003

ppa. 

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Dirk Schade
Director of Research and Development

ppa. 

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Dieter Fottner
Technical Production Manager



Certificate of Conformity

Dermatological Diagnostic Instruments (replaces issue of 8.11.2006)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.
Dermatoscope	Delta 10	K-0*.34.00*
	Delta 20	K-08.34.201
	mini 2000	D-01.78.100
	mini 3000	D-01.78.10*
	alpha+	D-0*.84.1**
Photo Adaptor for Delta 20		K-00.34.23*
Video-Dermatoscope		K-02.34.03*
Special Camera	Dermaphot	K-171.00.101
Optics Body	Dermaphot	K-00.34.1**
Adaptor cord		X-00.99.231
SLR Photo Adaptor		K-00.34.18*

Herrsching, 1. Oct. 2007

ppa. *Dirk Schade*

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Dirk Schade
Director of Research and Development

Claudia Schwieger

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Claudia Schwieger
Director of Quality Management



Kientalstr. 7
82211 Herrsching



Certificate of Conformity

Sphygmomanometers and Stethoscopes (replaces issue of 10.3.2004)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in according to Appendix IX, rule 1, 2, 3 and 12, in Class I. Conformity is assured according to the guidelines set out in appendix VII. Additional requirements for a measuring device assured according to appendix II.3.

Aneroid Sphygmomanometers	Gamma 3.0 - Gamma 5.5	Cat.-No. M-00.09.21*
	Gamma ST	Cat.-No. M-00.09.27*
	Gamma XXL	Cat.-No. M-00.09.30*
	Gamma XXL LF	Cat.-No. M-00.09.315
	Gamma G5, G7	Cat.-No. M-00.09.23*
	Gamma GST	Cat.-No. M-00.09.271
	Gamma GP	Cat.-No. M-00.09.240
	Gamma G5, G7 SPRI	Cat.-No. M-00.09.25*
	Gamma GP SPRI	Cat.-No. M-00.09.260
Cuffs for Gamma Sphygmomanometers		Cat.-No. M-00.09.6**
Cuffs for Gamma G-Sphygmomanometers		Cat.-No. M-00.09.6**
Cuffs for Gamma G SPRI-Sphygmomanometers		Cat.-No. M-00.09.7**
Service Case for Gamma G		Cat.-No. M-00.09.14*
PC Interface	Memotronic Profile	Cat.-No. M-00.09.151
Stethoscopes	Gamma 1.1 - 1.3	Cat.-No. M-00.09.91*
	Gamma 2.1 - 2.3	Cat.-No. M-00.09.92*
	Gamma C	Cat.-No. M-00.09.931
Replacement Parts: Cuffs, Rubber Bladders, Pressure Balls		Cat.-No. M-00.09.0**

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in according to Appendix IX, rule 10 in Class IIa. Conformity is assured according to the guidelines set out in appendix VII. Additional requirements for a measuring device assured according to appendix II.3.


Electronic Sphygmomanometer	MemoTronic PC2	Cat.-No. M-00.09.152
	Gamma E60	Cat.-No. M-00.09.160

Applied Standards

EN 1041:1998, EN 1441:1998, ISO 14971-1:1998, IEC 60601-1:1996, EN ISO 10993

Where applicable: EN 1060-1:1995, EN 1060-2:1996, EN 1060-3:1997, IEC 60601-1-2:1993

Herrsching, 5.4.2004

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Dirk Schade
Director of Research and Development

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Dieter Fottner
Technical Production Manager

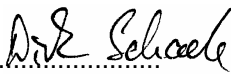
**Certificate of Conformity**

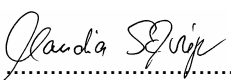
Handles and Bulbs (replaces issue of 24.07.2003)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.
Battery handle	mini 2000	D-01.79.009
Battery handle	mini 3000	D-01.79.02*
Battery handle	alpha+	D-01.89.051
Rechargeable handle	alpha+	D-02.89.053
Compact handle	-	X-01.99.105
Compact rechargeable handle	-	X-0*.99.471
Battery handle	BETA	X-01.99.118
Cord handle	BETA	X-00.99.212
Rechargeable handle	BETA NT 3,5 V	X-02.99.411
Rechargeable handle	BETA R 3,5 V	X-02.99.376
Rechargeable handle	BETA TR 3,5 V	X-02.99.384
Large battery handle	-	X-01.99.120
Lamp handle	-	X-04.99.60*
Bulbs	XHL	X-0*.88.***
mini-c Griff	-	D-01.79.03*

Herrsching, 20. Sept. 2006

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Dirk Schade
Director of Research and Development


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Claudia Schwieger
Director of Quality Management

**Certificate of Conformity**

Rechargeable batteries (Replaces issue of 20.9.2005)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42 EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.
Rechargeable battery	M2Z	D-01.89.013
Rechargeable battery	S2Z	X-01.99.333
Rechargeable battery	NT 2,5 V	X-01.99.433
Rechargeable battery	S3Z	X-02.99.314
Rechargeable battery	3,5 V NiMH	X-02.99.382
Rechargeable battery	M3Z	X-02.99.106
Rechargeable battery	S5Z	X-04.99.623
Rechargeable battery	HC 6V	X-04.99.624
Rechargeable battery	3.5 V Li-ion	X-07.99.381
Rechargeable battery	NiMH 6V	X-04.99.641
Rechargeable battery	Li-ion for mPack	X-07.99.675
Rechargeable battery	Li-Pol für mPack UNPLUGGED	X-07.99.680
Rechargeable battery	K3Z NiMH	X-02.99.393

Herrsching, den 1. Oct. 2007

ppa.

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Dirk Schade
Director of Research and Development.....
Claudia Schwieger
Director of Quality Management



Kientalstr. 7
82211 Herrsching



Certificate of Conformity

(replaces issue of 20.10.1999)

We certify that the following product conforms to the specifications of the Medical Device Directive 93/42 EEC and is registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description	Type	Cat. No.
Custom charger	NT 200	X-00.99.406

Applied Standards

EN 1041:1998, EN 1441:1998, ISO 14971-1:1998, IEC 60601-1:1996

Herrsching, den 24.7.2003

ppa. *Dirk Schade*

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Dirk Schade
Director of Research and Development

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Dieter Fottner
Technical Production Manager



Certificate of Conformity

Power Supplies and Chargers (Replaces issue of 20.9.2006)


We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

Article description

Cat. No.

Wall transformer	EN 80	X-95.12.118
Wall transformer, basic unit	EN 90	X-95.12.100
Wall transformer, extension unit	EN 90	X-95.12.125
Table-top transformer	EN 20-1	X-95.17.200
Wall transformer	EN 100	X-95.12.110
Extension unit	EN 100	X-95.12.135
Single-unit	EN 100-1	X-95.12.109
Wall transformer	EN 30	X-95.17.100
Plug-in transformer	E 7	X-95.16.100
Plug-in transformer	E 8	X-95.16.201
Table-top transformer	E 9	X-95.13.200
Charger	NT 200	X-00.99.40*
Rechargeable handle	BETA R 3,5 V	X-02.99.376
Rechargeable handle with transformer	BETA TR 3,5 V	X-02.99.384
Plug-in transformer with control unit	EN 15	X-95.16.302
Portable power supply	Accubox II/Accubox II-L	X-04.99.638/645
Plug-in transformer	E 10	X-00.99.328
Plug-in transformer for 3S LED-Headlight		X-95.16.310
Extension cord	-	X-00.99.207 (SA)
Wall/Table transformer base unit/with mPack/with control unit	EN 50	X-95.17.30*
Control unit for EN 50		X-95.17.305
Transformer with headband rheostat	HC 50	X-95.16.322
Power supply mPack with Li-ion battery	mPack	X-07.99.67*
HC-Converter	HC-Converter	X-95.17.308
EN 50 UNPLUGGED		X-95.17.310
mPack UNPLUGGED		X-07.99.665

Herrsching, 1. Oct. 2007

ppa. 

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Dirk Schade
Director of Research and Development



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Claudia Schwieger
Director of Quality Management



Kientalstr. 7
82211 Herrsching



Certificate of Conformity

Light sources and accessories (replaces issue of 16.12.2002)

We certify that the following products conform to the specifications of the Medical Device Directive 93/42/EEC and are registered in Class I according to appendix IX. Conformity is assured according to the guidelines set out in appendix VII.

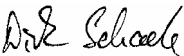
Article description	Type	Cat. No.
Fiber optics projector	HK 4000	Y-96.15.100
Fiber optics projector	HK 6000	Y-96.15.101
Fiber optics projector	HK 7000	Y-96.15.121
Fiber optics projector	HK 7000 D	Y-96.15.124
Fiber optics projector	Xenon 1000	Y-96.15.117
Xenon 1000 bulb		Y-96.15.108
Fiber Optics Cable	-	Y-03.99.518
F.O. Adaptors	-	Y-96.12.1**
Wheeled Floor Stand	-	Y-96.50.00*

Applied Standards


EN 1041:1998, EN 1441:1998, ISO 14971-1:2001, IEC 60601-1:1996

Where applicable: IEC 60601-1-2:1993, UL 2601-1:1994, CAN/CSA C22.2 No. 601.1-M90

Herrsching, 24.07.2003

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Dirk Schade
Director of Research and Development

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Dieter Fottner
Technical Production Manager