HEINE BETA X
Otoscope

DATA

Description	HEINE BETA X Otoscope 3x	HEINE BETA X Otoscope 4.2x
Catalogue number	B-130.28.330	B-131.28.330
Items included	HEINE BETA X Otoscope with HEINE X CHANGE System 3x Magnifier, 10x AllSpec 4 mm disposable tips, hard case, USB-C-cable with IEC 60601-1 approved power supply and country adapters	HEINE BETA X Otoscope with HEINE X CHANGE System 4.2x Magnifier, 10x AllSpec 4 mm disposable tips, hard case, USB-C-cable with IEC 60601-1 approved power supply and country adapters
Document release date	March, 2025	

MECHANICAL

Weight product	112 g	118 g
Weight battery	22 g	22 g
Weight packaging (including product)	734 g	740 g
Dimensions product	180 x 39 x 53 mm	180 x 39 x 53 mm
Dimension packaging	221 x 63 x 216 mm	221 x 63 x 216 mm
Connections	USB-C port	USB-C port
Imprints	front: HEINE logo, BETA X; icons: HEINE inSPECT, otoscopy light, on | off back: HEINE made in Germany side: USB-C, 5 V, 500 mA, IFU, MD, CE, production year, UDI, serial number, www.heine.com, datamatrix code, type BF applied part eyepiece attachment: HEINE X CHANGE System 3x Magnifier	front: HEINE logo, BETA X; icons: HEINE inSPECT, otoscopy light, on | off back: HEINE made in Germany side: USB-C, 5 V, 500 mA, IFU, MD, CE, production year, UDI, serial number, www.heine.com, datamatrix code, type BF applied part eyepiece attachment: HEINE X CHANGE System 4.2x Magnifier

ELECTRICAL

Power supply	Li-ion cell (internal battery)
Input	5 V DC, 500 mA
Power consumption	max. 1 W
Operating time	typ. 220 min. with 100 % brightness
Charging time	typ. 160 min.
Automatic switch-off function	turns off after 5 min.
Protection class	charging: II; operating: internally powered

HEINE inSPECT Additional Examination Light

OPTICAL

Type	HEINE LED illumination (HQ)
Illuminance	typ. 21.000 lx at 100 mm distance
Color temperature	3.500 K +/- 500 K
Color rendering index (CRI)	typ. CRI > 90
Working distance	50 to 100 mm

Classification according to IEC 62471	risk group 2 (moderate risk)
Optical safety according to ISO 15004-2	group 2
Optical safety according to ANSI Z80.36	group 2

Otoscopy light (F.O.)

OPTICAL	
Type	HEINE LED illumination (HQ)
Luminous flux (without | with 4 mm | 2.5 mm tip)	typ. 18 lm | 4.4 lm | 1.6 lm
Color temperature	3.500 K +/- 500 K
Color rendering index (CRI)	typ. CRI > 90
Classification according to IEC 62471	risk group 2 (moderate risk)

GENERAL	
Material	anodized aluminium, plastic, glass, coated silicone
REACH | RoHS	conform
Phthalate	contains no phthalate
Latex	contains no latex
Biocompatibility	conform
Environmental conditions operation	temperature: +10 °C to +35 °C, relative humidity: 30 % to 75 %, air pressure: 700 hPa to 1060 hPa
Environmental conditions storage	temperature: +5 °C to +45 °C, relative humidity: 45 % to 80 %, air pressure: 500 hPa to 1060 hPa
Environmental conditions transport	temperature: -20 °C to +50 °C, relative humidity: 10 % to 90 %, air pressure: 500 hPa to 1060 hPa
Instructions for use *	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues
Operating elements	3 control buttons: 1. HEINE inSPECT on-low | on-high brightness level; 2. otoscopy light on-high | on-low brightness level; 3. otoscope on-high brightness level | off
Accessories	please see the corresponding accessories online at www.heine.com/BETA-X-otoscope-accessories-IFU
Maintenance	device is maintenance-free
Service	device is service-free | change of rechargeable battery

HYGIENIC REPROCESSING	
Procedure	please see detailed description for the reprocessing procedure online at www.heine.com

CODES		
Customs code (tariff number)	90189084	
GTIN	4053755202904	4053755202911
Traceability	UDI code	
Country of origin	Germany (DE)	

REGULATORY	
Product classification (EU)	class I
Product classification (USA)	class I, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	otoscope: 12-849
	eyepiece attachment: 15-652
GMDN code	otoscope: 12849
	eyepiece attachment: 65448
Regulation number (FDA)	8744770
Product code (FDA)	ERA

FULLFILLS THE REQUIREMENTS OF DIRECTIVES & STANDARDS

ISO 13485	Medical devices - quality management systems - requirements for regulatory purposes
Regulation (EU) 2017/745	European regulation for medical devices
IEC 60601-1	Medical electrical equipment: general requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests
ISO 14971	Medical devices - application of risk management to medical devices
IEC 60601-1-6	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
IEC 60601-2-18	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 62366-1	Medical devices - part 1: application of usability engineering to medical devices
IEC 62471	Photobiological safety of lamps and lamp systems
ISO 15004-2	Ophthalmic instruments - fundamental requirements and test methods - part 2: light hazard protection
ANSI Z80.36	Ophthalmics - light hazard protection for ophthalmic instruments
IEC 62304	Medical device software - software life-cycle processes
ISO 10993-1	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
IEC 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes – safety requirements for portable sealed secondary lithium cells and for batteries made from them, for use in portable applications – part 2: lithium systems
UN transport test	UN transport test, section 38.3 lithium ion batteries | part III
IEC 60601-1-9	Medical electrical equipment - part 1-9: general requirements for basic safety and essential performance - collateral standard: requirements for environmentally conscious design
ISO 17664-2	Processing of health care products - information to be provided by the medical device manufacturer for the processing of medical devices - part 2: non-critical medical devices
ISO 2248	Packaging; complete, filled transport packages; vertical impact test by dropping
Directive (2011/65/EU) ROHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive (2012/19/EU) WEEE	Waste of electrical and electronic equipment
Regulation (1907/2006) REACH	Registration, evaluation, authorization and restriction of chemicals
Directive (2006/66/EC) battery | acc. waste	Batteries and accumulators and waste batteries and accumulators, German registration no. DE 48554371
Directive (94/62/EC) packaging | packaging waste	Packaging and packaging waste, German registration no. DE 5329703000126

*) further languages on request

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We reserve the right to change specification without notice.