HEINE BETA ⅏ Ophthalmoscope

DATA	
Description	HEINE BETA ⅏ Ophthalmoscope
Catalogue number	C-130.28.330
Items included	HEINE BETA ⅏ Ophthalmoscope, hard case, USB-C-cable with IEC 60601-1 approved power supply and country adapters
Document release date	March, 2025

MECHANICAL	
Weight product	150 g
Weight battery	22 g
Weight packaging (including product)	775 g
Dimensions product	200 x 48 x 31 mm
Dimension packaging	221 x 63 x 216 mm
Connections	USB-C port
Imprints	front: HEINE logo, BETA ⅏, icon: on | off; back: HEINE made in Germany, icons: different apertures and filters, focusCONTROL F | C; side: USB-C, 5 V, 500 mA, MD, production year, CE, serial number, www.heine.com, datamatrix code

ELECTRICAL	
Power supply	Li-ion cell (internal battery)
Input	5 V DC, 500 mA
Power consumption	max. 1 W
Operating time	typ. 240 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

OPTICAL	
Type	HEINE LED illumination (HQ)
Magnification	ca. 15x for emmetropic patient
Diopter	+38 D to -36 D
Optical system	AOS+ (Aspherical Optical System)
Colour temperature	typ. 3 500 K
Color rendering index (CRI)	typ. CRI 93
Field of view	9° with largest aperture
Working distance	fundus: ≈20 mm, cornea: ≈50 mm
Pupil size	min. 2 mm; opt. ≥4 mm
Filters	red-free, polarisation, blue
Apertures	7 luminous field apertures with separate red-free and polarisation filter: cobalt blue filter, fixation star with polar coordinates, large spot, small spot, pinhole, slit, hemispot
Focus switch	HEINE focusCONTROL: switch between anterior (C: cornea) and posterior segment (F: fundus) of the eye

Classification according to ISO 10942	group A
Classification according to IEC 62471	risk group 2 (moderate risk)
Optical safety according to ANSI Z80.36	group 2
Optical safety according to ISO 15004-2	group 2

GENERAL

Material	anodized aluminium, plastic, glass
REACH | RoHS	conform
Phthalate	contains no phthalate
Latex	contains no latex
Biocompatibility	conform
Environmental conditions operation	temperature: + 10 °C to +35 °C, relative humidity: 10 % 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	illumination control wheel, diopter adjustment wheel, aperture wheel, filter switch, focusCONTROL switch
Display	indirect illuminated index of refraction
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)	90185090
GTIN	4053755203031
Traceability	UDI code
Country of origin	Germany

REGULATORY

Product classification (EU)	class I
Product classification (USA)	class II, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	12-817
GMDN code	46786
Regulation number (FDA)	886.1570
Product code (FDA)	HLJ

FULFILLS 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
ISO 10993-1	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
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 62366-1	Medical devices - part 1: application of usability engineering to medical devices
DIN EN 15004-1	Ophthalmic instruments - fundamental requirements and test methods - part 1: general requirements applicable to all ophthalmic instruments
DIN EN 15004-2	Ophthalmic instruments - fundamental requirements and test methods - part 2: light hazard protection
ANSI Z80.36	Ophthalmics - light hazard protection for ophthalmic instruments
ISO 10942	Ophthalmic instruments - direct ophthalmoscopes
IEC 62471	Photobiological safety of lamps and lamp systems
IEC 62304	Medical device software - software life-cycle processes
IEC 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes - safety requirements for portable sealed secondary 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 (94/62/EC) packaging | packaging waste	Packaging and packaging waste, German registration no. DE 5329703000126
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

*) further languages on request

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