HEINE BETA® 200 LED VET F.O. otoscope.

DATA

Description	HEINE BETA 200 LED VET F.O. otoscope
Catalogue number	see catalogue or price list
Document release date	June, 2024

GENERAL

Product variants	BETA 200 LED VET F.O. otoscope 2.5 V BETA 200 LED VET F.O. otoscope 3.5 V
Material	plastic, metal, glass
REACH | RoHS	conform
Phthalate	contains no phthalates that require declaration
Latex	contains no latex
Biocompatibility	conform
Surface	plastic, metal, glass
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: 45 % to 80 %, air pressure: 500 hPa to 1060 hPa
Instructions for use***	Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Português
Operating elements	swivelling viewing window
Power supply	HEINE rechargeable handles (3.5 V), HEINE battery handles (2.5 V), HEINE EN 200 wall transformer
Removable parts | accessories	HEINE reusable SANALON S specula, insufflation bulb

MECHANICAL

Weight product	90 g
Weight packaging (including product)	145 g
Dimensions product	74 x 35 x 47 mm (height x width x depth)
Dimensions packaging	108 x 42 x 68 mm (length x height x depth)
Connections	AV for rechargeable handle, bayonet for tip, fitting for insufflation tube
Imprints	BETA 200 LED VET, HEINE made in Germany, symbol for application part BF, CE, data matrix code, serial number, www.heine.com
Enclosure rating	IP40

ELECTRICAL - RECHARGEABLE HANDLE	
Input voltage	3.0 - 3.7 V DC
Power consumption	max. 350 mA
Operation time	approx. 7 h using fully loaded Li-ion L rechargeable battery (X-007.99.383)
Protection class	charging: II, operating: internally powered

ELECTRICAL - BATTERY HANDLE	
Input voltage	1.8 V - 3.2 V
Power consumption	typ. 373 mA at full brightness and 3.2 V
Operation time	n/a
Protection class	internally powered

OPTICAL	
Type	LED illumination (HQ) 3.5 V | 2.5 V
Luminous flux* (without | with 5 mm tip)	typ. 17.5 lm | typ. 0.8 lm | 0.4 lm
Illuminance** (with 5 mm tip)	typ. 30,000 lx
Color temperature	3500 K +/- 500 K
Color rendering index	typ. CRI 92
Lifetime	typ. 100,000 h
Classification according to IEC 62471	exempt
Magnification	2.5-fold

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

CODES	
Customs code	90189084
GTIN	4053755131488 (BETA 200 LED VET otoscope 2.5 V) 4053755131518 (BETA 200 LED VET otoscope 3.5 V)
Traceability	UDI-code
Country of origin	Germany (DE)

REGULATORY	
Product classification (EU)	n/a
Product classification (USA)	class I, 510(k) exempt
Product classification (Canada)	n/a
UMDNS code	n/a
GMDNS code	12849
Regulation number (FDA)	874.4770
Product code (FDA)	ERA

FULFILLS THE REQUIREMENTS OF DIRECTIVES & STANDARDS

ISO 13485	medical devices - quality management systems - requirements for regulatory purposes
IEC 60601-1	medical electrical equipment: general requirements for basic safety and essential performance
IEC 60601-2-18	medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
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
IEC 62471	photobiological safety of lamps and lamp systems
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 10993-1	biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
ISO 17664	processing of health care products - information to be provided by the medical device manufacturer for the processing of medical devices
ISO 2248	packaging; complete, filled transport packages, vertical impact test by dropping
Directive (2014/35/EU)	making available on the market of electrical equipment designed for use within certain voltage limits.
Directive (2011/65/EU) ROHS	on the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive (2012/19/EU) WEEE	on waste electrical and electronic equipment
Regulation (1907/2006) REACH	registration, evaluation, authorization and restriction of chemicals
Directive (94/62/EC) packaging | packaging waste	packaging and packaging waste, German registration no. DE 5329703000126

*) at 3.7 V supply voltage
**) calculated
***) further languages on request

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