HEINE mini 3000® LED F.O. otoscope.



DATA

Description	mini 3000 LED F.O. otoscope
Catalogue number	see catalogue or price list
Document release date	July, 2024

GENERAL

Product variants	mini 3000 LED F.O. otoscope, black mini 3000 LED F.O. otoscope, blue
Material	plastic, metal
REACH | RoHS	conform
Phthalate	contains no phthalates that require declaration
Latex	contains no latex
Biocompatibility	conform
Surface	plastic, metal
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
Durability	5 years warranty
Instructions for use*	Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Português
Operating elements	swivelling viewing window
Power supply	HEINE mini 3000 battery handle (2.5 V)
Removable parts | accessories	HEINE AllSpec disposable tips, reusable tips, insufflation bulb
Features	shock-resistant polycarbonate housing, fade out function, connector for pneumatic test
Maintenance	device is maintenance-free, LED cannot be replaced by the user
Service	device is service-free
Patents	n/a

MECHANICAL

Weight product	40 g
Weight packaging (including product)	95 g
Dimensions product	59 x 27 x 45 mm (height x width x depth)
Dimensions packaging	108 x 42 x 68 mm (length x height x depth)
Connections	screwed thread connector to handle, bayonet for tip, insufflation port connector
Imprints	mini 3000 F.O. LED data matrix code
	HEINE made in Germany, symbol for application part BF, CE, HEINE logo, serial number, www.heine.com

ELECTRICAL - BATTERY HANDLE

Input voltage	1.2 V - 3.2 V
Power consumption	typ. 155 mA at full brightness and 3.2 V
Operation time	typ. 10 h using 2x IEC LR6 1.5 V (size AA) batteries
Protection class	internally powered

OPTICAL

Type	LED illumination (HQ) 2.5 V
Magnification	3-fold
Luminous flux** (without | with 4 mm tip)	typ. 8 lm | typ. 1.4 lm
Illuminance*** (with 4 mm tip)	typ. 100,000 lx
Colour temperature	4000 K +/- 500 K
Colour rendering index (CRI)	typ. CRI 92
Medium life expectancy (LED)	typ. 50,000 h
Classification according to IEC 62471	excempt

HYGIENIC REPROCESSING

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

CODES

Customs code	90189084
GTIN	4053755158591 (black) 4053755158607 (blue)
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	12-849
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
Regulation (EU) 2017/745	on medical devices
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 (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

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

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We reserve the right to change specification without notice.

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