HEINE mini 3000® Otoscope with XHL illumination

Viewing window with 3x magnification produces distortion-free images of the examined object.

Permanently attached swivelling viewing window allows for instrument use, and cannot be misplaced or lost.

Bright and homogeneous illumination with excellent colour rendering.

DATA	
Description	HEINE mini 3000 Otoscope
Catalogue Number	D-001.70.206
Revision / Date	12.12.2018

MECHANICAL	
Weight	50 g instrument incl. bulb, additional 90 g battery handle with 2 batteries
Dimensions product	56 x 25 x 40 mm
Dimensions packaging	108 x 69 x 40 mm
Connections	Screwed thread connector to handle
Imprints	Product name, HEINE logo, HEINE-made-in-Germany, CE, BF symbol
Protection class	N/A

ELECTRICAL	
Power supply	HEINE mini 3000 battery handle (can be loaded with 2pcs of dry cell batteries or 1pc HEINE NiMH 2Z rechargable battery with HEINE miniNT
Operating time	Up to 2,5h battery powered / 1 hour NiMH powered
Charging time	See mini3000 battery handle

OPTICAL	
Type	XHL
Luminous flux	typ. 1.75 lm without tip, typ. 0,5 lm with 4 mm tip
Illuminance *	typ. 40.000 lx with 4 mm tip
Medium life expectancy (XHL)	typ. 10 h
Classification according to IEC 62471	Exempt

GENERAL	
Material	Brass body coated with ultramid synthetics and pearled metal parts, magnifying lens consisting of Polycarbonate, (Handle: chrome-finish upper section, refined plastic)
REACH/RoHS	Conform
Phthalate	Product is phthalate free
Latex	Product is latex free
Biocompatibility	Conform
Surface	Metal parts are perlescent chrome-plated, plastic is matt black, magnifier colorless transparent
Guarantee	5 years
Environmental conditions operation	10 °C to 35 °C, 30 % to 75 % rel. humidity, 700 hPa to 1060 hPa
Environmental conditions storage	5 °C to 45 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa
Environmental conditions transport	-20 °C to 50 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa
Instructions for use	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues **
Operating elements	Undetachable rotable magnifying lens
Accessories	Reusable tips, AllSpec disposable tips, mini 3000 battery handle
Maintenance	Battery change, instrument is maintenance free
Service	Device is service free

HYGIENIC REPROCESSING	
Procedure	Housing can be cleaned and disinfected manually (wipe clean and wipe disinfect). Please see detailed description in the accompanying documents

* calculated
** further languages on request

CODES	
Customs Code (tariff number)	90189084
GTIN	4053755124275
Country of origin	Germany

REGULATORY	
Product classification (EU)	Class I
Product classification (USA)	Class 1
Product classification (Canada)	Class I
UMDNS Code	12-849
GMDNS Code	12849
Regulation Number (FDA)	8744770
Product Code (FDA)	ERA

Fulfills the requirements of Directives & Standards	
ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
Directive 93/42/EEC	Concerning 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 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
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 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