HEINE mini 3000® LED Ophthalmoscope

DATA

Description	HEINE mini 3000 LED Ophthalmoscope
Catalogue number	see catalogue or price list
Document release date	August, 2025

MECHANICAL

Weight product	40 g
Weight packaging (including product)	90 g
Dimensions product	69 x 34 x 24 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, serial number

ELECTRICAL

Power supply	HEINE mini 3000 Battery Handle
Input	2.5 V: max. 450 mA
Operating time	typ. 10 h (battery handle)
Protection class	internally powered

OPTICAL

Type	HEINE LED illumination (HQ)
Optical system	condenser (PMMA acrylglas), objectiv (PS polystrol), front mirror (silicate, 96% reflection, with quartz protection coat)
Illuminance	typ. 470 lx in 200 mm
Colour temperature	4.000 K ± 500 K
Color rendering index (CRI)	typ. 92
Intensity decrease	fade out (adaption of intensity to charge of battery)
Field of view	11.3°
Aperture	large spot, small spot, hemispot
Filters	fixation star with grey filter, red free filter
Diopter	+20D to -20D
Light controlling	fade out (adaption of intensity to charge of battery)
Classification according to ISO 10942	group B
Optical safety according to ISO 15004-2	group 2

GENERAL

Material	plastic, metal, glass
REACH | RoHS	conform
Latex	contains no latex
Biocompatibility	conform
Surface	plastic matt black, chrome-plated, scratch-resistant surface
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, Français, Español, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Português
Operating elements	lens wheel, aperture wheel
Removable parts | accessories	HEINE mini 3000 Battery Handle, HEINE mini 3000 Charging Handle
Maintenance	device is maintenance-free, change of battery (handle)
Service	device is service-free

HYGIENIC REPROCESSING

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

CODES

Customs code (tariff number)	90185090
GTIN	4053755158713
Traceability	serial number
Country of origin	Germany

REGULATORY

Product classification (EU)	class I
Product classification (USA)	class 2, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	12-817
GMDN code	46786
Regulation number (FDA)	886.1570
Product code (FDA)	HLJ

FULFILS 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 (MDR)
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
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

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

*) further languages on request

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We reserve the right to change specification without notice.

QUALITY
MADE IN GERMANY