

The HEINE DELTA 30 PRO dermatoscope.



DATA

Description	DELTA 30 PRO
Catalogue number	K-235.28.305
Item included in following catalogue numbers	DELTA 30 PRO with contact plate with scale, USB cord with medical approved plug-in power supply, hard case
Date	Sep, 2023

ACCESSORIES

Description	HEINE diSTANCE
	The working ring enables the user to examine and manage a lesion under magnification without contact
Catalogue number	K-000.34.103
Description	Small contact plate
	For the examination of difficult-to-access pigmented lesions
Catalogue number	K-000.34.206

MECHANICAL

Weight product	0.275 kg
Weight packing including product	0.900 kg
Dimensions product	195 x 55 x 70 mm
Dimensions packing	260 x 190 x 90 mm
Connections	USB-C port, mounting for mobile phone covers, connection to Charger 30
Imprints	Instrument: product name, HEINE logo, MD, production date, CE, GTIN, serial number, www.heine.com, datamatrix code, symbols, power supply, optics specification, scale
Enclosure rating	IP 20

ELECTRICAL

Power supply	Li-ion Cell (internal battery)
Input	USB-C: 5 V DC, 1.2 A HEINE Charger 30: See datasheet of charger
Power consumption	max. 6W
Operating time	> 210 min. @ 5300 K, polarised, 100% Brightness
Charging time	USB: typ. 150 min. HEINE Charger 30: typ. 150 min.
Protection class	Charging: II; Operating: internally powered

OPTICAL

Type	HEINE LED illumination (HQ)
Magnification	10-fold
Diopter	-4 to +4 dpt
Optical system	Achromatic system, 3 elements
Illuminance	Typ. > 22000 lx in 15 mm distance without contact plate
Colour temperature	Typ. 5300 K to 6500 K to 8300 K to 11000 K
Color rendering index (CRI)	Typ. ≥ 85 @ 8300 K
Medium life expectancy (LED)	Typ. > 50000 h
Lens diameter	Typ. 32 mm
Antireflection coating	Loupe optics multilayer coating R < 0,5% per optical surface Contact plate inside surface multilayer coating R < 0,5%, outside surface no coating
Working distance	15 mm distance in non-contact mode, contact to skin in contact mode
Filters	Linear and cross polarisation
Resolution	Typ. 40 LP/mm in image center with 80% contrast at 50 mm observation distance
Light controlling	Brightness, Polarisation, colour temperature
Classification according to IEC 62471	Group 1

GENERAL

Material	Plastic, metal, glass
REACH/RoHS	Conform
Biocompatibility	Conform
Environmental conditions operation	10 °C to +35 °C, 30 % to 75 % rel. humidity, 700 hPa to 1060 hPa
Environmental conditions storage	Less than 1 month at a temperature: -20°C to +50 °C Less than 3 months at a temperature: -20°C to +40 °C Less than 1 year at a temperature: -20°C to +20 °C rel. humidity: < 70% 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	Power switch, brightness control in 3 stages, colour temperature control in 4 steps, polarisation switch, diopter adjustment wheel, charging indicator, polarisation indicator
Removable parts / accessories	Contact plate with scale, mobile phone covers for Apple® iPhone, universal smartphone adapter
Maintenance	Device is service-free
Service	Device is service-free / Change of rechargeable battery

HYGIENIC REPROCESSING

Procedure	Please see detailed description in the reprocessing procedure
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CODES

Customs code (tariff number)	90189084
GTIN	4053755201549
Traceability	UDI Code
Country of origin	DE

REGULATORY

Product classification (EU)	Class I
Product classification (USA)	Class I, 510(k) exempt
Product classification (Canada)	Class I
UMDNS code	18-021
GMDNS code	18021
Regulation number (FDA)	880.6350
Product code (FDA)	KYT
Contact plates	According to article 120 section 3 of the MDR (EU) 2017/745, a transition period for the contact plates is available. The contact plates could be placed on the market until 26 May 2024 under the directive 93/42/EEC

FULFILLS THE REQUIREMENTS OF DIRECTIVES & STANDARDS

ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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
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 62304	Medical device software - Software life-cycle processes
IEC 62133	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
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	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	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
Directive (2006/66/EC) Battery / Acc. Waste	Batteries and accumulators and waste batteries and accumulators, German registration no. DE 48554371
Directive (94/62/EC) Packaging / Packaging Waste	Packaging and packaging waste, German registration no. DE 5329703000126

**) further languages on request