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	Feb, 2024

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-000.24.207

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, 10 % to 75 % rel. humidity, 700 hPa to 1060 hPa
Environmental conditions storage	Less than 1 month at a temperature: +5°C to +50 °C Less than 3 months at a temperature: +5°C to +40 °C Less than 1 year at a temperature: +5°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

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

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