HEINE DELTA*one* Dermatoscope

DATA	
Description	DELTA*one*
Item included in following catalogue numbers	K-210.28.305 - DELTAone STANDARD EDITION
Date	October 01, 2019

MECHANICAL	
Dimensions product	LxWxH 128x57x40 mm
Connections	Micro USB port, mounting for mounting case smartphone
Imprints	Instrument: product name, HEINE logo, CE, production date, serial number, www.heine.com, datamatrix code, symbols, power supply, optics specification
Protection class	IP20

ELECTRICAL	
Power supply	Li-ion Cell (internal battery)
Input	USB 2.0 Micro B: 5 V DC, 650 mA
Power consumption	Max. 3.25 W
Operating time with max energy consumption	Typ. 80 min
Operating time with min energy consumption	Typ. 460 min
Avg. working time before charging *	5 days
Charging time	USB: typ. 75 min
Safety 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. > 17 000 lx in 15 mm distance without contact plate
Colour temperature	Typ. 5 700 K
Color rendering index (CRI)	Typ. ≥ 90
Medium life expectancy (LED)	Typ. > 50 000 h
Lense diameter	22 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 Polarisation plate inner / outer side no coating
Working distance	15 mm distance in non-contact mode, contact to skin in contact mode
Contact / non-contact mode	Can be used in contact and non-contact mode
Resolution	40 LP/mm in image center with 80% contrast at 50 mm observation distance
Classification according to IEC 62471	Group I

APP & SOFTWARE	
Operating system	Requires iOS 12 or later
Updates	Software updates are distributed via app store and must be installed as soon as they are available
Image format	PNG, JPEG
Special features	aCapture, management and classification of dermatoscopic images, patient management, skin cancer screening assistent, image sharing, autofocus

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*) based on average energy consumption and based on average daily use in a clinical practice.

GENERAL	
Material	Plastic, metal, glass
REACH/RoHS	Conform
Phthalate	Contains no phthalate
Latex	Contains no latex
Biocompatibility	Conform
Surface	Plastic ,metal, glass
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	Power switch, brightness control in 3 stages, polarisation switch, diopter adjustment wheel, charging indicator, polarisation indicator
Removable parts / accessories	Contact plate with scale, mounting case smartphone for Apple® iPhone XR, XS ***
Maintenance	Device is maintenance-free
Service	Device is service-free
Patents	N/a

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

CODES	
Customs code (tariff number)	90189084
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

Fulfills the Requirements of Directives & Standards	
ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
Directive 93/42/EEC	European directive 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

**) further languages on request

***) The Apple iPhone is not included in the scope of delivery.
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