HEINE CC1 charging case

DATA	
Description	Charging Case
Catalogue number	X-000.99.091
Date	January 20, 2021

MECHANICAL	
Weight product	23 g
Weight packing including product	81 g
Dimensions product	72,69 x 46,37 x 17,28 mm
Dimensions packaging	110 x 70 x 40 mm
Connections	USB type C port, battery connector
Imprints	Instrument: HEINE logo, power supply; Instrument label: product name, HEINE logo, UDI, CE, production date, serial number, www.heine.com

ELECTRICAL	
Power supply	External power supply
Input	USB 2.0 Type C: 5 V, 1.2 A
Power consumption	max. 6 W
Charging time, standard battery	typ. 1.5 h
Safety class	class II

GENERAL	
Material	Plastic
REACH/RoHS	Conform
Phthalate	Contains no phthalate
Latex	Contains no latex
Biocompatibility	Conform
Surface	Plastic
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	Charge status indicator
Removable parts/accessories	Removable battery
Maintenance	Maintenance free
Service	Service free
Patents	N/a

HYGIENIC REPROCESSING	
Procedure	Please see detailed description in the reprocessing procedure

CODES	
GTIN	4053755198429
Customs code (tariff number)	90189084
Country of origin	DE
Traceability	UDI Code

*) further languages on request

REGULATORY	
Product classification (EU)	Class I
Product classification (USA)	n/a
Product classification (Canada)	Class I
UMDNS code	17-115
GMDNS code	17115
Regulation number (FDA)	n/a
Product code (FDA)	n/a

Fulfills the Requirements of Directives & Standards	
Directive 93/42/EEC or Regulation (EU) 2017/745	European directive for medical devices or Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
EN 1041	Information supplied by the manufacturer of medical devices
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
ISO 14971	Medical devices - Application of risk management to medical devices
ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 17664	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 22248	Packaging; complete, filled transport packages; vertical impact test by dropping
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
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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
IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 62304	Medical device software - Software life-cycle processes
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