HEINE AllSpec® disposable tips.

DATA

Description	HEINE AllSpec® disposable tips - single use plastic tips for HEINE otoscopes, different sizes for infants and adults
Catalogue number	Infants 2.5 mm Ø: pack of 1000 pcs. B-000.11.128 dispenser pack of 250 pcs. B-000.11.153 Adults 4 mm Ø: pack of 1000 pcs. B-000.11.127 dispenser pack of 250 pcs. B-000.11.152
Date	March, 2024

MECHANICAL

Weight product	50 pcs. incl. bag 22 g
Weight packing including product	Pack of 1000 pcs. (Ø 2.5 mm) 515 g | dispenser pack of 250 pcs. (Ø 2.5 mm) 160 g
Dimensions product	Infants: Ø proximal 17.5 mm, Ø distal 2.5 mm, lenght 36 mm Adults: Ø proximal 17.5 mm, Ø distal 4 mm, lenght 30.5 mm
Dimensions packing	Pack of 1000 pcs. 250 x 125 x 65 mm | dispenser pack of 250 pcs. 115 x 115 x 115 mm
Connections	Fits all HEINE F.O. otoscopes, with HEINE tip adaptor also suitable for HEINE BETA 100 and HEINE K100 otoscopes (*)
Imprints	HEINE, CE, single-use symbol (molded-in proximal on the outside)

GENERAL

Material	Styrol made of at least 94 % recycled material
REACH | RoHS	REACH: nothing to declare according to Article 33, RoHS: not applicable due to detachable part
Phthalate	Contains no phthalates that require declaration
Latex	Contains no latex
Biocompatibility	Conform
Surface	Dark gray
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	Please see instructions for use for the otoscopes
Patents	N/a

HYGIENIC REPROCESSING

Procedure	None, product is single-use

CODES

Customs code (tariff number)	90189084
GTIN	Infants 2.5 mm Ø: pack of 1000 pcs. (B-000.11.128): 4053755113897 Adults 4 mm Ø: pack of 1000 pcs. (B-000.11.127): 4053755113866
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	13-662
GMDNS code	34897
Regulation number (FDA)	874.4770
Product code (FDA)	ERA

FULFILLS THE REQUIREMENTS OF DIRECTIVES & STANDARDS

ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
Regulation (EU) 2017/745	Medical device regulation
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 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 2248	Packaging; complete, filled transport packages; vertical impact test by dropping
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
Regulation (1907/2006) REACH	Registration, evaluation, authorization and restriction of chemicals

(*) HEINE BETA 100 and HEINE K100 otoscopes no longer available

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