

# HEINE AllSpec®

## Disposable Tips



pack of 250 pcs.



pack of 1000 pcs.

### 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	July, 2025

### MECHANICAL

Weight product	50 pcs. incl. bag 22 g
Weight packaging (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 packaging	pack of 1000 pcs. 250 x 125 x 65 mm   dispenser pack of 250 pcs. 115 x 115 x 115 mm
Connections	fits all current HEINE 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
Shelf Life	5 years
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
GMDN 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 Oscopes no longer available

