

## Technical Data and security sheet Disposable eartips

Réf. N°: 24 700 25/40; 24 701 25/40; 24 710 25/40; 24 720 25/40

Created: 05/12/12 Update: 04/03/15 Index: c

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Device class : Classe 1
Period : Temporary (Rule 1)

• No. of record ANSM: B.I-07823-95

• GMDN Code : 35348

Applied rule ( annex IX)

Invasive
 Non therapeutic action
 Non Medical action

- diagnostic action

General description	Single use plast	ic eartips, each size and	l colour to be set on an	otoscope, different ve	ersion.	
Enclosed documentation	Yes	Picture and technical scheme.				
Batch reference number	No					
Connected device	Yes	Linking to an otoscope from following brands: Heine, Kawe, Gima, Holtex, Riester, Welsh Allyn and Pakistani-made.				
Single Use Device	Yes	mono patient during use, then disposable. Do not re-use.				
Sterile Device	No					
Stérilization	Yes	With ethylene oxide and chemical. Not with hot air or gamma, sterilize before use, single use device can't be sterilized after use.				
Autoclavable	No					
Cleaning	Yes	With a solution which is not hurtful to PS, with detergent or soapy water				
Unsuitable substances		to PS like acetone, benzene, chloroform.				
Product components	No					
Materials	Polystyrene (PS at 1.5%.	styrene (PS) ½ choc DowPS 485 71 natural BG 1444. Colouring agent BASF Liqui Kolor VL2786 5%.				
Contains Latex	No					
Labeling	Yes	On the box or bag CE/ name/ REF./material, single use.				
Packing	Yes	Carton box of 250 pcs or sealed bag of 50 pcs or 1000 pcs				
Particular storage	Yes	Dry and clean				
Shelf Life	Temporary, les	s than 30 minutes.				
Marking on the Medical Device	Yes	COMED and CE				
Références + extension		24 700 25/40	24 701 25/40	24 710 25/40	24 720 25/40	
Désignation		Heine+Kawe+P Small 2.5mm and 4 mm	Heine + Kawe+P Big 2.5mm and 4 mm	Riester 2.5mm and 4mm	Welsh Allyn 2.5mm and 4 mm	
Dimensions (mm)	Dimensions (mm)		See anex 1			
Temperature resistance (C°)		Max = + 40 Min = - 10				
Flexibility reversion rate		Flexible				
Thickness (mm)		1.5	0.5	0.5	0.5	
<i>Net Weight (g)+- 1%</i>		1	1.2	1	1	
Colors		Grey/green/red/yell ow/blue - opaque	Opaque black	Opaque light grey	Opaque black	
Use			inside the ear with an o	otoscope.		
Instructions for use		Take an eartip and put it on an otoscope, for models 24 701 XX clip it on otoscope, for models 24 700 XX bayonet fixing. After use throw it in a medical waste container. Single use device no sterile.				
Use care		This device can be used only by a competent and qualified person. To be single used by person, it is recommended to use one eartip per ear per patient to avoid ear/ear contaminations on the same person. Do never put the eartip until the bottom in the ear, respect the appropriate distance with the bottom of the ear, perforation risk. Right maintain the head of the patient to avoid any inappropriate movement. Single use device, do not re-use, cross contamination risk with another patient.				
Recycling		Yes		•		

Editor: Laura HEINRICH

Function : QA Paraph : LH COMED sas 8 Rue Louise Michel 67200 STRASBOURG France www.comed.fr



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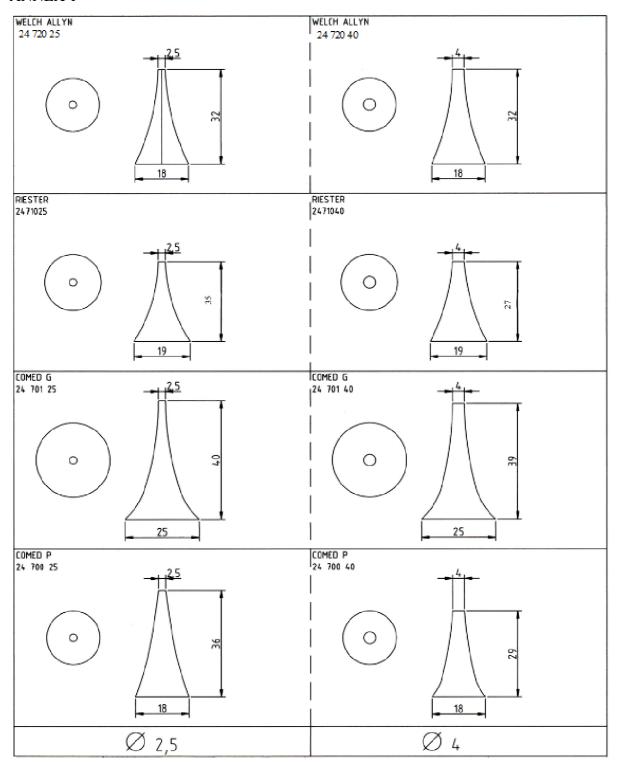
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Recovery	In medical waste containers.	
DEEE/REACH	No/ Exempted	
Phthalates	No	
Security data	Phrases R = Blank Phrases combination = Blank	

## ANNEX 1



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