

- 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 surgical      | - Non Medical action     |
| - diagnostic action |                          |

<i>General description</i>	Single use plastic eartips, each size and colour to be set on an otoscope, different version.			
<i>Enclosed documentation</i>	Yes	Picture and technical scheme.		
<i>Batch reference number</i>	No			
<i>Connected device</i>	Yes	Linking to an otoscope from following brands: Heine, Kawe, Gima, Holtex, Riester, Welsh Allyn and Pakistani-made.		
<i>Single Use Device</i>	Yes	mono patient during use, then disposable. Do not re-use.		
<i>Sterile Device</i>	No			
<i>Stérilization</i>	Yes	With ethylene oxide and chemical. Not with hot air or gamma, sterilize before use, single use device can't be sterilized after use.		
<i>Autoclavable</i>	No			
<i>Cleaning</i>	Yes	With a solution which is not hurtful to PS, with detergent or soapy water		
<i>Unsuitable substances</i>	Product hurtful to PS like acetone, benzene, chloroform.			
<i>Product components</i>	No			
<i>Materials</i>	Polystyrene (PS) ½ choc DowPS 485 71 natural BG 1444. Colouring agent BASF Liqui Kolor VL2786 at 1.5%.			
<i>Contains Latex</i>	No			
<i>Labeling</i>	Yes	On the box or bag CE/ name/ REF./material, single use.		
<i>Packing</i>	Yes	Carton box of 250 pcs or sealed bag of 50 pcs or 1000 pcs		
<i>Particular storage</i>	Yes	Dry and clean		
<i>Shelf Life</i>	Temporary, less than 30 minutes.			
<i>Marking on the Medical Device</i>	Yes	COMED and CE		
<i>Références + extension</i>	24 700 25/40	24 701 25/40	24 710 25/40	24 720 25/40
<i>Désignation</i>	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
<i>Dimensions (mm)</i>	See anex 1			
<i>Temperature resistance (C°)</i>	Max = + 40 Min = - 10			
<i>Flexibility reversion rate</i>	Flexible			
<i>Thickness (mm)</i>	1.5	0.5	0.5	0.5
<i>Net Weight (g)+- 1%</i>	1	1.2	1	1
<i>Colors</i>	Grey/green/red/yell ow/blue - opaque	Opaque black	Opaque light grey	Opaque black
<i>Use</i>	Device used to look inside the ear with an otoscope.			
<i>Instructions for use</i>	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.			
<i>Use care</i>	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.			
<i>Recycling</i>	Yes			

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

ANNEX 1

