

- Classification of device: Class I
- Duration: Temporary (rule 1)
- ANSM registration no.: BI01739-99
- GMDN code:

Rule applied (year IX)

- | | |
|-----------------------|------------------------|
| - Non-invasive | - No Therapeutic Asset |
| - Non-surgical | - No Medical Asset |
| - No diagnostic asset | |

<i>General description</i>	Ocular foreign body extractor formed of a metal center tube, a magnetic metal tip and a metal tip with a Nylon loop. Model with magnifying glass attached on the tube.	
<i>Attachments</i>	Yes	Photo
<i>Lot reference</i>	No	
<i>Device connected</i>	No	
<i>Single use device</i>	No	
<i>Sterile device</i>	No	
<i>Sterilization</i>	Yes	With ethylene oxide and chemical. Not with hot air or gamma
<i>Autoclavable</i>	Yes	At 121° C.
<i>Cleaning</i>	Yes	With a solution that does not attack the metal and nylon, with detergent.
<i>Unsuitable substance</i>	Product attacking the metal or nylon such as acetone Benzene, hydrocarbon	
<i>Component parts</i>	Yes	Magnetic metal tip, tip with nylon loop, tubular central body, loop with magnifying glass
<i>Contents</i>	Tips and central body made of stainless steel, loop made of nylon, magnifying glass made of glass.	
<i>Labeling</i>	Yes	On the bag CE/name/Ref./COMED.
<i>Packaging</i>	Yes	Plastic pouch.
<i>Special storage</i>	Yes	Dry and clean
<i>Duration of use</i>	Average	
<i>Marking on DM</i>	Yes	CE/COMED/REF/STAINLESS STEEL/SUPPLIER CODE + ODR No.
<i>References + extensions</i>	33 430 00	33 450 00
<i>Designation</i>	magnet	With magnifying glass
<i>Dimensions L x B x H (mm)+. 3mm</i>	70 + 21 + 10	70 + 21 + 10 x 20
<i>Net weight (g)+. 1%</i>	28	42
<i>Colors</i>	metal	metal
<i>Head diameter (mm)</i>	8.30	8.30
<i>Temperature resistance (C°)</i>	- 40 to 80° C	- 40 to 80° C
<i>Use</i>	Allows you to remove superficial foreign bodies from the eye, either metallic by the magnetic tip or other substances with the loop.	
<i>Instructions for use</i>	Take the handle and use the required side according to the foreign body to be removed. Turn the side to use by unscrewing it from the handle. If metallic foreign body, use the magnetic side, for other foreign bodies use the side with the Nylon loop. Cannot be used for embedded foreign bodies but only for superficial foreign bodies on the eye. After use, clean with a disinfectant and screw the side used on the handle (upside down). Use the model with magnifying glass for small foreign bodies. Do not push for if the body is difficult to extract, see an ophthalmologist.	
<i>Precaution for use and/or single use warning</i>	This device can be used only by a competent and qualified person. Thoroughly clean the tips of the device before first use. Check before each use that the tips are well clean/disinfected and in good condition without splinters. Risks of eye damage. In the case of embedding, do not try to remove the body, immediately consult an ophthalmologist.	
<i>Recycling</i>	No	
<i>Disposal</i>	In household garbage bins.	
<i>WEEE/REACH</i>	No	
<i>Safety data</i>	Phrases R = Null Combination of phrases = Null	
<i>Applicable standards</i>	NF EN ISO 9001: 2008 ; NF EN 1041: 2008 + A1: 2013; NF EN ISO 15223-1: 2012;	NF EN ISO 13485 : 2012; NF EN ISO 14971 : 2013; NF ISO 15223-2: 2010

33 430 00



33 450 00

