

- Classification of device: Class I
- Duration: Temporary (rule 1)
- ANSM registration no.: FR/CA01/1010713V
- GMDN code: 32789

*Rule applied (annex IX)*

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

<i>General description</i>	Plastic eye patch for visual testing.	
<i>Attachments</i>	Yes	Photo, technical drawing.
<i>Lot reference</i>	No	
<i>Device connected</i>	Yes	Indirectly connected to visual testing.
<i>Single use device</i>	No	
<i>Sterile device</i>	No	
<i>Sterilization</i>	No	
<i>Autoclavable</i>	No	
<i>Cleaning</i>	Yes	With soapy water or detergent by hand or in machine
<i>Unsuitable substance</i>	Product attacking PMMA like Ketone, halogen, aromatic hydrocarbons.	
<i>Component parts</i>	No	
<i>Contents</i>	Made of 4mm white PMMA (Polymethylmethacrylate (C5O2H8)n)	
<i>Phthalates</i>	No	
<i>Labeling</i>	Yes	Description, reference, size, CE, COMED name
<i>Packaging</i>	Yes	Plastic film unit
<i>Special storage</i>	No	
<i>Marking on DM</i>	Yes	CE, name, Reference.
<i>References + extensions</i>	32 830 00	32 831 00
<i>Dimensions L x B x H (mm)+- 3mm</i>	244 x 22	290 x 95
<i>Thickness (mm)</i>	4	4
<i>Net weight (g)+- 1%</i>	32	93
<i>Colors</i>	Bright white	
<i>Patch diameter (mm)</i>	61	33
<i>Temperature resistance (C°)</i>	- 40 to + 50 at 90° C	
<i>Density (g/cm<sup>3</sup>)</i>	1.19	
<i>Traction resistance (Mpa)</i>	80	
<i>Use</i>	Allows you to patch an eye during a remote visual testing.	
<i>Instructions for use</i>	A medical device used during visual examination. Take the device and place it in front of the eye to patch, repeat the operation with the other eye. Clean and remove the protective film before first use.	
<i>Precaution for use and/or single use warning</i>	Check before use if the eye patch has been cleaned properly among each patient. Check if the edges are well not sharp or not cutting.	
<i>Recycling</i>	Yes	
<i>Disposal</i>	The eye patch can be recycled in plastic containers to be rebuilt or depolymerization.	
<i>WEEE/REACH</i>	No/No	
<i>Safety data</i>	Phrases R = Null    Combination of phrases = Null	
<i>Applicable standards</i>	NF EN ISO 9001: 2008 ;                      NF EN ISO 13485 : 2012; NF EN 1041: 2008 + A1: 2013;          NF EN ISO 14971 : 2013; NF EN ISO 15223-1: 2012;                NF ISO 15223-2: 2010	