

Identification Bracelets Safety and Data Sheet

Ref. No.: 16 105 46/ 16 106 40/ 16 106 41

TCE3

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<i>General description</i>	Inviolable identification bracelets for adults and children over 2 years old		
<i>Class of DM</i>	Is not considered a Medical device, no CE marking		
<i>Attachments</i>	Yes	Photo and technical drawing	
<i>Lot reference</i>	Yes	See on the box	
<i>Device connected</i>	No		
<i>Single use device</i>	Yes	Mono patient during use and then disposable	
<i>Sterile device</i>	No		
<i>Sterilization</i>	Yes	With ethylene oxide and chemical. Not with gamma or hot air	
<i>Autoclavable</i>	No		
<i>Cleaning</i>	Yes	With a solution not attacking the PVC, with detergent	
<i>Unsuitable substance</i>	Product attacking the PVC such as acetone, benzene, chloroform.		
<i>Component parts</i>	Yes	A bracelet, a label and a permanent pen.	
<i>Contents</i>	Made of PVC for the bracelet and made of paper for the label. Hypoallergenic.		
<i>Contains latex</i>	No		
<i>Standard</i>	EN 71		
<i>Labeling</i>	Yes	Name, reference, lot, single use, quantity.	
<i>Packaging</i>	Yes	Cardboard box of 100 bracelets.	
<i>Special storage</i>	Yes	Dry and clean.	
<i>Duration of use</i>	Average		
<i>Marking on DM</i>	No		
<i>References + extensions</i>	16 105 46	16 106 40	16 106 41
<i>Designation</i>	Adult	Pink children	Blue children
<i>Dimensions L x W x H (mm)+- 3mm</i>	250 x 25 x 12	170 x 19 x 12	
<i>Diameter of use (mm)</i>	Min = 20 ; Max = 70	Min = 20 ; Max = 45	
<i>Thickness (mm)</i>	0.5		
<i>Net weight per 100 g (g)</i>	232		
<i>Colors</i>	transparent	pink	blue
<i>Temperature resistance (°C)</i>	-20 to +70°C		
<i>Rate of flexibility reversibility</i>	Rigid		
<i>Use</i>	Inviolable device allowing identification of persons		
<i>Instructions for use</i>	<p>1/ Take a bracelet and enter the person's name either on the label or directly on the bracelet, by the window, with the felt in permanently writing.</p> <p>2/ Insert the label with the inscription on the side of transparent plastic to the end and hold on to the detachable part, then detach the detachable end.</p> <p>3/ Put the bracelet around the part to identify by keeping the transparent side towards the exterior to be able to read the name.</p> <p>4/ Select the desired length by inserting the tip into the selected hole depending on the diameter of the part to identify.</p> <p>5/ Pull down the locking clip on the sprocket by tightening hard until sound of the locking clip is heard. Check if it is well installed.</p> <p>6/ Cut the remaining strip if necessary by taking care not to leave sharp edges.</p> <p>7/ To remove the bracelet, cut the strip with suitable scissors.</p>		
<i>Precaution for use and/or single use warning</i>	<p>This device can be used only by a competent and qualified person.</p> <p>To be used as single use per person. Do not tighten the bracelet entirely but leave sufficient space, the bracelet must always be able to move around. Do not leave sharp edges. Properly check that the bracelet is closed by lightly pulling on and that it cannot slip out of the wrist. Do not heat the device or leave it on the skin in tight and permanent contact or on open wounds.</p>		
<i>Recycling</i>	Yes		
<i>Disposal</i>	In plastic waste bins		
<i>WEEE/REACH</i>	No/ NC		
<i>Phthalates /PVC</i>	No/ Yes		
<i>Safety data</i>	Phrases R = Null Combination of phrases = Null		