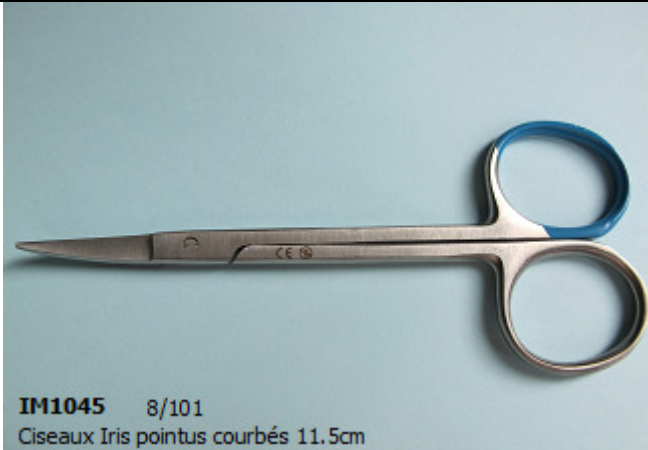
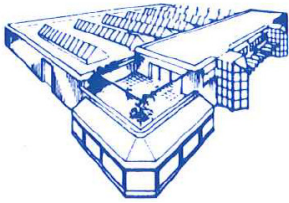


## PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	IRIS Scissor
I/2	General Description	IRIS Scissor, 11.5cm, curved
I/3	GMDN N°	35325
I/4	Reference Number	8001753
I/5	Class	<input type="checkbox"/> I <input type="checkbox"/> Is <input checked="" type="checkbox"/> IIa According to Directive 93/42/EEC - Annex IX, Rules 6
I/6	Notify Body	CE <sub>0120</sub>
I/7	Composition Raw Material	Stainless Steel 420
I/8	Sterile	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No  If, yes <input checked="" type="checkbox"/> ETO <input type="checkbox"/> Gamma <input type="checkbox"/> Steam
I/9	First Packaging	Number of pieces in Packaging:    1 piece per peel pack
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	Cut the thin tissues during the surgery or to cutting the suture Alone, single use and transient use (<60min)
II/2	User:	Medical staff or professional
II/3	Contraindication of use	Not use If the device is dirty or visual defects If packaging is damaged or open do not use. Sterile unless package is damaged.
II/4	Special requirement for use	n/a
II/5	Handling and storage conditions:	Standard condition or atmospheric condition

III- Supplementary information		
III/1	Compatibility with others medical devices (in the set)	n/a
III/2	Device contents animal substances	No
III/3	Device contents medicinal substances	No
III/4	Device comes into contact with substances	No
III/5	Used with Accessories	No
III/6	Used in combination with other Medical Device	No



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IV- MANUFACTURING		
IV/1	Manufacturing Operations <input checked="" type="checkbox"/> peel pack <input type="checkbox"/> pouches <input type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input checked="" type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization	1 pieces per peel pack  50 peel packs per cartons
IV/2	Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1 <ul style="list-style-type: none"> <li>Name and description of product</li> <li>Name and address of manufacturer</li> <li>LOT N°</li> <li>Article N°</li> <li>Year of manufacturing</li> <li>Expiry date</li> <li>Quantity</li> <li>Sterile</li> <li>Method of sterilisation</li> <li>Indication for single use</li> <li>Not use if the pack is opened</li> <li>CE 0120</li> </ul>	Example of a label Ciseaux 1 Ciseaux Iris 11.5cm, courbé 50 Peelpacks/carton  <div style="display: flex; justify-content: space-between;"> <div> <p><b>REF</b> 8001753</p> <p> 2018-12</p> <p><b>LOT</b> 13.12.17</p> </div> <div style="text-align: right;"> <p>Applimed SA            Pra de Plan 1            CH-1618 Châtel-St-Denis</p> </div> </div> <div style="text-align: center;"> <p>(01)07640103630051(17)181217(10)131217</p> </div>
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)

