
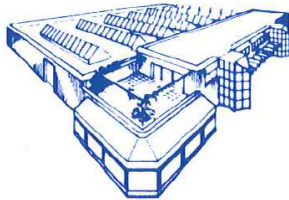


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Scissor
I/2	General Description	Nail Scissor, 11.5 cm
I/3	GMDN N°	38820
I/4	Reference Number	8001917
I/5	Class	<input type="checkbox"/> I <input checked="" type="checkbox"/> Is <input type="checkbox"/> IIa According to Directive 93/42/EEC - Annex IX, Rules 1
I/6	Notify Body	CE ₀₁₂₀
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 nails. 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 conditions or atmospheric conditions








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	YES (usual substances used for treatment and cleaning of wounds)
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 25 peel packs per box 4 boxes per cartons
IV/2	<p>Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1</p> <ul style="list-style-type: none"> Name and description of product Name and address of manufacturer LOT N° Article N° Expiry date Quantity Sterile Method of sterilisation Indication for single use Not use if the pack is opened CE 0120 	<p style="text-align: right;">Example of a label</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Ciseaux 1 Ciseaux à ongles 11.5cm 25 Peelpacks/carton 4 Cartons/carton</p> <p>Nagelschere 11.5 cm stumpf, gebogen 1 Stk/Peelpack 25 Peelpacks/Schachtel</p> <p>Distributor: Kuhn und Bieri AG- 3098 Köniz - www.kuhnbieteri.ch</p> <p>      </p> </div> <div style="width: 35%; text-align: right;"> <p>IN150701</p>  <p>REF 8001917</p> <p> 2018-11</p> <p>LOT 13.11.18</p> <p>Applied SA Pra de Plan 1 CH-1618 Châtel-St-Denis</p> <p style="text-align: right;">SD</p> </div> </div>	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	