

APPLIMED SA

Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

# PRODUCT DATA

| I-Product Description & Classification | | |
|---|---|---|
| I/1 | Designation | Irrigation Cannula |
| I/2 | General Description | Irrigation Cannula, Straight, 120mm, 15G |
| I/3 | GMDN N° | 30889 |
| I/4 | Reference Number | 8001843 |
| I/5 | Class | ☐ I ☐ Is ☒ IIa<br>According to Directive 93/42/EEC - Annex IX, Rules 6 |
| I/6 | Notify Body | **CE**0120 |
| I/7 | Composition Raw Material | Stainless Steel 304/Cr |
| I/8 | Sterile | ☒ Yes ☐ No<br><br>If, yes<br>☒ ETO ☐ Gamma ☐ Steam |
| I/9 | First Packaging | Number of pieces in Packaging: 1 piece per peel pack |
| I/10 | Picture |  |

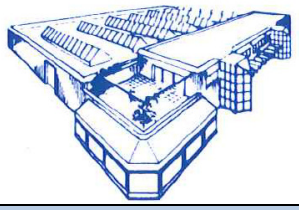
| II- Description of use and operating of device | | |
|---|---|---|
| II/1 | Intended use/indication: | This medical device is a surgical instrument used for the cleaning and irrigation of the wound. The olive protects the tissues against the needle tip.<br>Single use and transient Use (<60min) |
| II/2 | User: | Medical staff or professional |
| II/3 | Contraindication of use | Not use, if the device is dirty or visual defects<br>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 |

APPLIMED SA

Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch



## IV- MANUFACTURING

| | | | |
|---|---|---|---|
| **IV/1** | Manufacturing Operations | ☒ peel pack<br>☐ pouches<br>☒ boxes<br>☒ cartons<br>☒ cleaning<br>☒ sterilization | 1 pieces per peel pack<br><br>100 peel pack per box<br>10 boxes per cartons |
| **IV/2** | Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1<br>• Name and description of product<br>• Name and address of manufacturer<br>• LOT N°<br>• Article N°<br>• Expiry date<br>• Quantity<br>• Sterile<br>• Method of sterilisation<br>• Indication for single use<br>• Not use if the pack is opened<br>• CE 0120 | Example of a label<br>**Aiguille boutonnée**<br>1 Aiguille boutonnée 120mm, 15G<br>100 Peelpacks/boîte<br>10 Boîtes/carton<br>REF 8001843<br>2024-01<br>LOT 19.02.25<br>**Knopfkanüle LL 120mm, 15G**<br>1 Stk/Peelpack<br>100 Peelpacks/Schachtel<br>10 Schachteln/Karton<br>Distribué par MayBach<br>CE 0120 STERILE EO<br>Applimed SA<br>Pra de Plan 1<br>CH-1618 Châtel-St-Denis<br>(01)07640103637586(17)240125(10)190225 | |
| **IV/3** | Place of sterilisation: | ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande) | |