





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 | Wood Applicator | | | |
| I/2 | General Description | Applicator with Wooden Stick, 150x2.5 mm, Big Cotton head, Continental Shape | | | |
| I/3 | GMDN N° | 33954 | | | |
| I/4 | Reference Number | 1021275 | | | |
| 1/5 | Class | │ │ │ │ │ │ │ | | | |
| I/6 | Notify Body | CE | | | |
| 1/7 | Composition Raw Material | 100% cotton (head) and Wooden Stick | | | |
| I/8 | Sterile | ☐ Yes ☐ No | | | |
| | | If, yes ☐ ETO ☐ Gamma ☐ Steam | | | |
| I/9 | First Packaging | Number of pieces in Packaging: 50 pieces per pouch | | | |
| I/10 | Picture | WENT OF THE CONTROL O | | | |

| II- Description of use and operating of device | | | | |
|--|----------------------------------|--|--|--|
| II/1 | Intended use/indication: | A device intended used to apply a substance (eg medication) to the Ear/Nose/throat (ENT) treatment and to care the superficial wound for absorption, barrier or compressing. 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. | | |
| 11/4 | Special requirement for use | Warning: fragile product (can break). Handle with Care Should not be use with Alcohol | | |
| II/5 | Handling and storage conditions: | Standard conditions or atmospheric conditions | | |







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| III- Supplementary information | | | | | |
|--------------------------------|---|--|--|--|--|
| III/1 | Compatibility with others | n/a | | | |
| | medical devices (in the set) | | | | |
| III/2 | Device contents animal | NO | | | |
| | substances | | | | |
| III/3 | Device contents medicinal | NO | | | |
| | substances | | | | |
| III/4 | Device comes into contact with substances | Applimed has demonstrated compatibility with the following substances: - Water | | | |
| | with substances | - Peroxide water (3%) | | | |
| | | - Peroxide water (3 %) | | | |
| | | - Octenisept | | | |
| | | - Eosine | | | |
| | | - Merfen | | | |
| III/5 | Used with Accessories | NO | | | |
| III/6 | | | | | |
| 111/6 | Used in combination with | NO | | | |
| | other Medical Device | | | | |

| | IV- MANUFACTURING | | | | | | |
|------|-----------------------------|---|---|--|--|--|--|
| IV/1 | Manufacturing Operations | ☐ peel pack ☐ pouches/bags ☐ boxes ☐ cartons ☐ cleaning ☐ sterilization | 50 pieces per pouch 20 pouches per carton | | | | |
| IV/2 | | Applicateur book Applicateur grosse to Applicator bighead, Applikator Kontinent Aplicador forma contapplikator stort hove Applicatore a testa of Applicator grote kopplicator | tête continentale continental shape talform mit großem Kopf ntinental de cabeza grande ed kontinental form grande, forma continentale ontinental de cabeça grande o continentale vorm | | | | |
| IV/3 | Place of sterilisation: | n/a | | | | | |