

PILLOWCASE SPECIFICATION SHEET

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|---|--|
| 1. Name/designation: | Pillowcase |
| 2. Composition/materials: | PP (25-30 g/m ²) |
| 3. Reference: | 9507023 |
| 4. GMDN Code: | 18047 (Cover, pillow, protective) |
| 5. Medical device class: | Class I |
| 6. Intended use: | The device is intended to be used as a physical barrier on a pillow to prevent cross contamination. This device is single use. |
| 7. Explanation of class: | According to Rule 1 of Annex VIII (MDR 2017/745). |
| 8. Legal Manufacturer: | Xiantao Fortune Medical Supplies Co., Ltd.
No. 182 Hechang New Street, Pengchang Town, Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA |
| 9. European Representative:
(EC Rep) | SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel,
The Netherlands |
| 10. CH Representative:
(CH Rep) | SUNGO Technical Service Gmhb
Bahnhofstrasse 21, CH-6300 Zug, Switzerland |
| 11. Sterility: | This product is supplied non sterile. |
| 12. Recommended sterilization: | ETO (EO, Ethylene Oxide gas) *
* The devices do not need to be sterilized before use. |
| 13. Intended user: | This device is intended to be used solely by trained medical staff, e.g. medical doctors and nurses. |
| 14. Contraindications of use: | No known contraindications. |
| 15. Special requirements for use: | No special requirements. |
| 16. Warnings: | Do not reuse. |
| 17. Handling and storage: | The devices are not fragile. Store in an appropriately dry and cool place. Do not store under direct sunlight. |
| 18. Shelf life: | The legal manufacturer has established the shelf life of these devices to be 5 years. |

19. Example of the label:

Bag

Carton

REF 9507023

Taie d'oreiller en non tissé - 60x60cm
Kissenbezug Vliesstoff - 60x60cm
Non woven pillowcase - 60x60cm

1 pcs-Stk/sachet-Beutel-bag

2024-05 2029-05
CE MD LOT 2401039

EC REP SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands

Xiantao Fortune Medical Supplies Co., Ltd.
No. 182 Hechang New Street, Pengchang
Town, Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

CH REP

SUNGO Technical Service Gmhb
Bahnhofstrasse 21, CH- 6300 Zug
Switzerland



APPLIED SA
Prs de Plan 1
CH-1616 Châtel-St-Denis



REF 9507023

Taie d'oreiller en non tissé-60x60cm
Kissenbezug Vliesstoff-60x60cm
Non woven pillowcase-60x60cm

1 pcs-Stk/sachet-Beutel-bag

100 sachets-Beutel-bags/carton-Karton

2024-05 2029-05
CE MD LOT 2401039

EC REP SUNGO Europe B.V.
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20. Other information: The devices do not contain any substances derived from animal or human tissues or any medicinal substances. The devices do not contain any natural rubber or latex.
21. Instructions for use (IFU): No instructions for use are required as the devices can be used safely without them, taking into account the intended user' s training and knowledge, and the risk classification of the device (class I).

Pillowcase	
Dimensions	60±2 cm x 60±2 cm
Shape	Rectangle
Materials	PP (25-30 g/m ²)



		Signature	Date		
1pc/bag	Drawer	Green zhu	11/28/2024		
100bags/carton	Auditor	Myning Shen	11/28/2024	Caption	
	Auditor	June Zhang	11/28/2024	No	
Version	2	Approval	Fred zhu	11/28/2024	Page 2/2