

PRODUCT SPECIFICATION

| Product Category | Ophthalmic Drapes |
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| Туре | Ophthalmic Drape 100 cm x 120 cm with collection pouch |
| Material | SMS 45 gsm |
| Ref. No. | 20054 |
| Intended Use | The Ophthalmic Drapes with one or two pouches are placed over |
| | the head of the patient. They have a slightly bigger fenestration |
| | area in order to let surgeons perform on patient's eye procedures |
| | such as cataract extraction. The existence of pouch(es) facilitates |
| | the collection of the fluids generated by the irrigation of solutions |
| | to the ophthalmic area during the surgical procedure. |
| Certification | CE 2803 |
| Classification | Class Is, according to Annex IX of Council Directive 93/42/EEC |
| Sterilization Method | EtO |
| Conformity | MEDDEV 2.4/1 Rev. 9 - June 2010 Rule 1 |
| Applicable Standards | ISO 9001, ISO 13485, ISO 14971, ISO 11607, ISO 10993, ISO |
| | 14698, ISO 11138, ISO 15223, ISO 11737, ISO 11135, ISO |
| | 14644 |
| Shape | |
| Primary Packing | Individually packed in pouch |
| Shelf life | 3 years |
| Storage Condition | Store at ambient temperature (below 37°C) and protect from |
| | moisture. |
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