

TECHNICAL DATA SHEET

**Description:**

59705: Absorbent Underleg Drape, Sterile

Dimensions:

Drape size: 158 x 235 cm

Reinforcement: 104 x 158 cm

Properties:

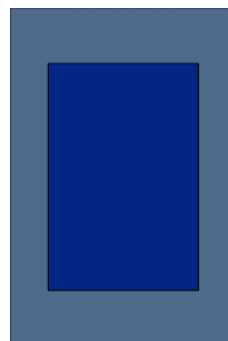
Basis weight/ thickness of base material:

SMS 47 g/m² + Film 25µm

Basis weight of reinforcement: 99 g/m²

High performance fabric as defined by EN 13795:2011

Test results as per EN13795 available upon request.

**Indication:**

To create a sterile field around the operative site and to cover areas of the body and operating room equipment that may or may not be involved in the surgical procedure. Single use product.

Counter indication:

None in particular.

Main materials:

Base material: SMS/Film (polypropylene/ LDPE).

Reinforcement: Control Plus SMF (polypropylene)

Does not contain Natural rubber latex.

Does not contain DEHP.

Sterilization:

Product is sterilized by ethylene oxide (ETO).

Packaging:

Shipping case of 14 units.

All units are placed within 1 polyethylene bag.

Unit packaging: CSR wrap, FFS (Form/Fill/Seal) peel-bag,

1 traceability sticker. Bar coding: GS1-128 symbology, linear on shipping case and unit packaging.

Manufacturing:

Processed in China of U.S. Materials.

The manufacturing site's quality system conforms to ISO13485.

Regulatory information:

Product CE marked as per 93/42/EEC Directive on Medical Devices.

Class of the device: I, sterile.

This product complies with EN 13795:2011.

Storage:

Store in a dry and cool place, away from intense sources of heat.

Keep as much as practicably possible in its shipper box.

Shelf life:

5 years, from date of manufacture.