

Date of printing: 08.11.2022

PRODUCT CODE: COS-47-0132.-2P
PRODUCT DESCRIPTION: surgical drape DS2 100x120cm,sterile

Risk Class: I nesterilní / I non-sterile

Quality certification: ISO 13485

Conformity to guidelines: Regulation MDR 2017/745

Shelf life (years): 5

Sterilization instructions: Product is compatible with ETO sterilization and must be sterilized in accordance with EN ISO 11135 (in the valid version).

Verified sterilization parameters:

- Temperature: 50°C +/- 5°C
- Humidity: 70% +/- 25%
- Vacuum level: 125mbar +/- 5mbar
- Exposure time: 4hours +/- 1min

Sterile supplied product is possible to resterilize 1 more time prior to its use.

Non-sterile supplied product is possible to sterilize 2 times prior to its use.

Product is dedicated for single use. It is not allowed to sterilize already used product.

Storage instructions: Storage temperature limit: +5°C / +30°C
Keep dry and out of direct sunlight

PRODUCT DEVELOPMENT / APPROVAL - RESPONSIBLE PERSON

Original bill of material created by:	Date of creation:	Original technological process created by:	Date of creation:	Bill of material approved by:	Date of last approval:	Technol. process approved by:	Date of last approval:
Píštěk Pavel	31.03.2022	Píštěk Pavel	31.03.2022	Dřimalová Iveta	13.04.2022	Dřimalová Iveta	13.04.2022

AMENDMENT RECORD:

Change Number: Product Code: Date of Change / Modification: Responsible Person: Change / Modification Approved By:

NO RECORDED AMENDMENT

APPROVAL OF SPECIFICATION:

Product Specification Approved By: Hrubá Gabriela

Date of last approval: 08.11.2022

PRODUCT CODE: PRODUCT DESCRIPTION:
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PACKAGING:
Case Quantity (Pcs): 80,00
Weight of Packaging (kg):

BILL OF MATERIAL:

Code:	Type:	Description of Item:	Size:	Unit:
P-20-0132-HH	Raw material	drape DS2,100x120 cm	1,000	pcs
SPE-21X25/30	Microtene Pouch:	PE pouch 21x25cm/30my	1,000	pcs
SMI-60X100/25	Microtene Pouch:	microtene pouch 60+(2x220)x100cm, 25um	1,000	pcs
KSB-VL5	Outer Box:	carton 39,3x33,8x26,5 cm, 5-layer, w/o printing, brown	1,000	pcs

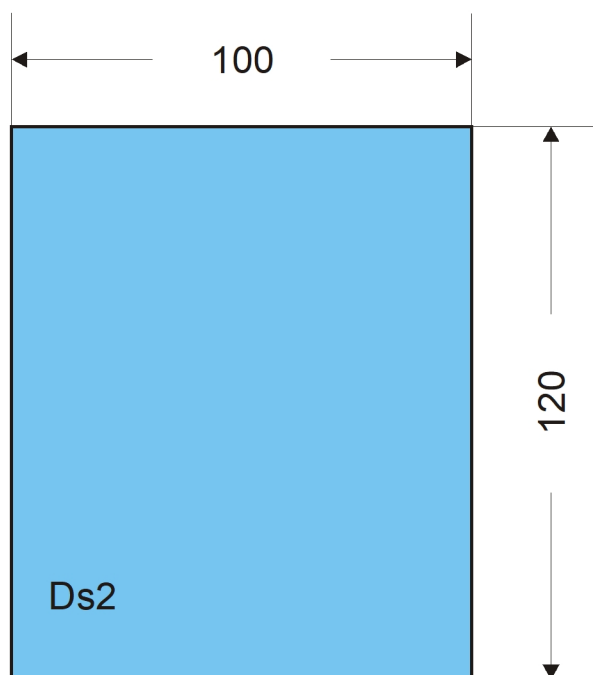
DRAWING:

PRODUCT CODE:

COS-47-0132.-2P

PRODUCT DESCRIPTION:

surgical drape DS2 100x120cm,sterile



FOLDING:

PRODUCT CODE:

COS-47-0132.-2P

PRODUCT DESCRIPTION:

surgical drape DS2 100x120cm,sterile

Folding Method: HS1

Width of Folded Product (cm): 20,00

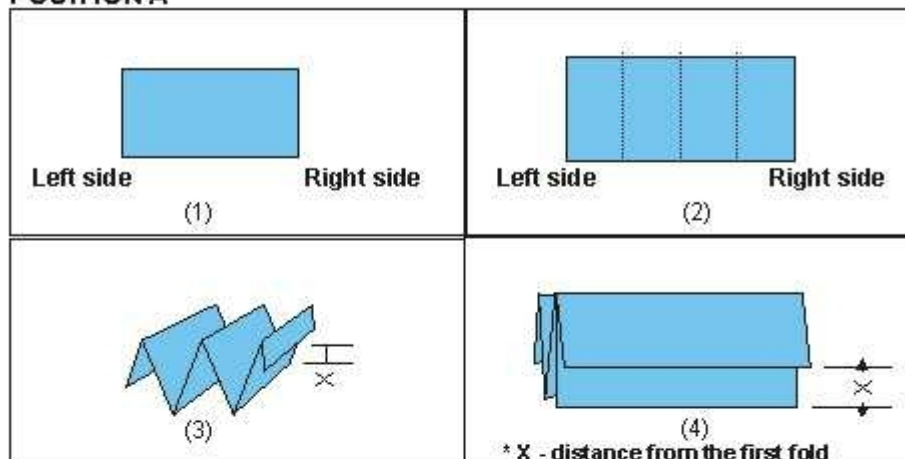
Height of Folded Product (cm): 10,00

FOLDING ACCORDING TO THE METHOD BELOW OR DESCRIPTION IN THE DRAWING ABOVE:

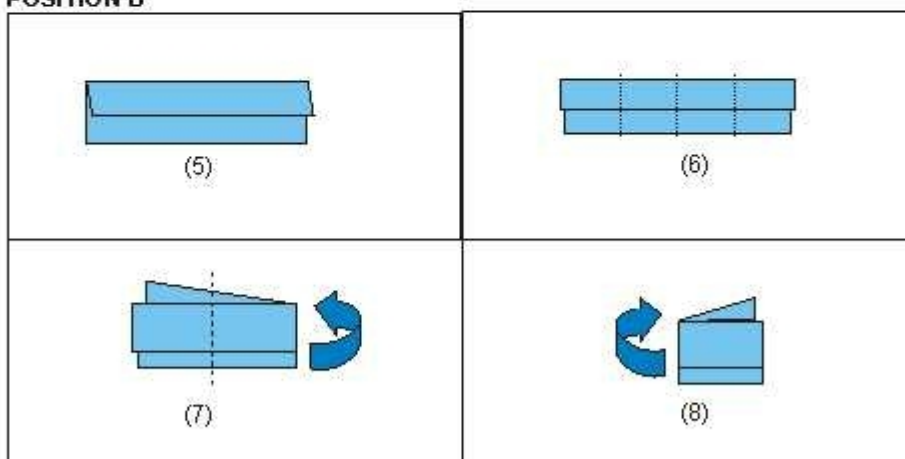
Unless there are limits of deviation for product dimensions stated in the drawing, the allowed limits are in compliance with the internal procedure PP01.

FOLDING TECHNIQUE HS1 (for automatic folding without adhesive tape)

POSITION A



POSITION B



FOLDING TECHNIQUES