Date of printing: 08.11.2022

PRODUCT CODE: **PRODUCT DESCRIPTION:**

COS-502-055.-2S **Mayo cover SMS 209x82cm,sterile**

Risk Class: I sterilní / I sterile

Quality certification: ISO 13485

Conformity to guidelines: Medical Device Directive 93/42/EEC

Shelf life (years): 3

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	Dřímalová Iveta	04.04.2022	Dřímalová Iveta	04.04.2022

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

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PRODUCT CODE: **PRODUCT DESCRIPTION:**

COS-502-055.-2S **Mayo cover SMS 209x82cm,sterile**

PACKAGING:

Case Quantity (Pcs): 45,00

Weight of Packaging (kg):

BILL OF MATERIAL:

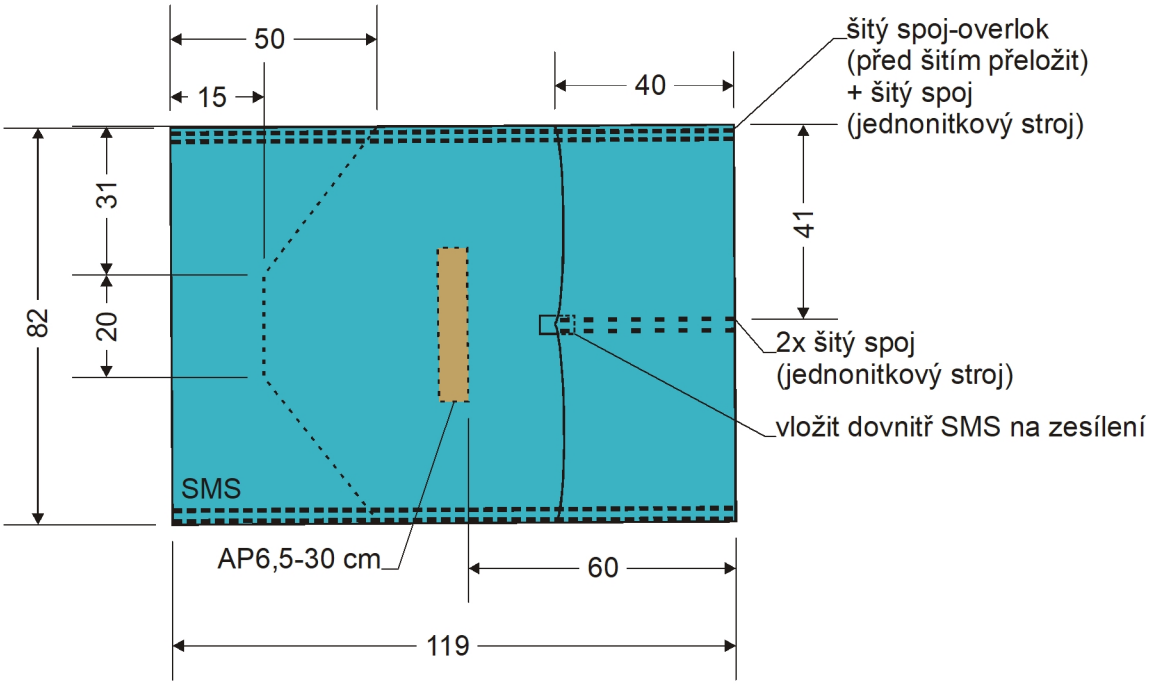
Code:	Type:	Description of Item:	Size:		Unit:
P-502-055	Semi Product:	Mayo cover SMS 209x82cm		1,000	pcs
SMS-M-240/50	Raw material	SMS, 240cm/50g, blue	209,00	82,000	cm
AP5-6/6,25 DH	Semi Product:	adhesive tape 5-6/6,25	6,25	30,000	cm
PRS-B-12,5/80	Raw material	80 gsm white glassine paper silicone coated 2 sides, the width 125 mm	6,25	1,000	m
LEP-002	Raw material	Technomelt PSM 8626 Dermatak		0,002	k
PEF-T-11/23	Raw material	PE foil Hostaphan, 11cm/23my, transparent, flat	5,50	1,000	m
LEP-001	Raw material	Technomelt DM 6990 Dispomelt		0,002	k
SMS-M-240/50	Raw material	SMS, 240cm/50g, blue	2,50	4,000	cm
SPE-21X25/30	Microtene Pouch:	PE pouch 21x25cm/30my		1,000	pcs
SPF-EO-25X40	Sterilization Pouch:	MM70-1/PP50-1 see-through-pouches 250 x 400		1,000	pcs
ERS-7X10/1	Label:	label in roll self-adhesive, 7x10 cm with 1 peel off field		1,000	pcs
KSF-VL5	Outer Box:	carton 57x38,5x29,5 cm, 5-layer, w/o printed, brown		1,000	pcs

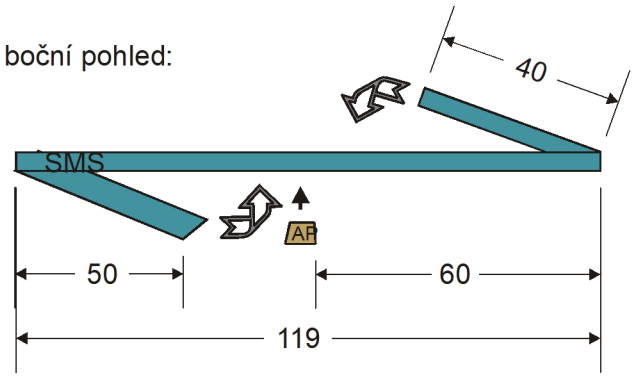
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DRAWING:

PRODUCT CODE: **PRODUCT DESCRIPTION:**

COS-502-055.-2S **Mayo cover SMS 209x82cm,sterile**



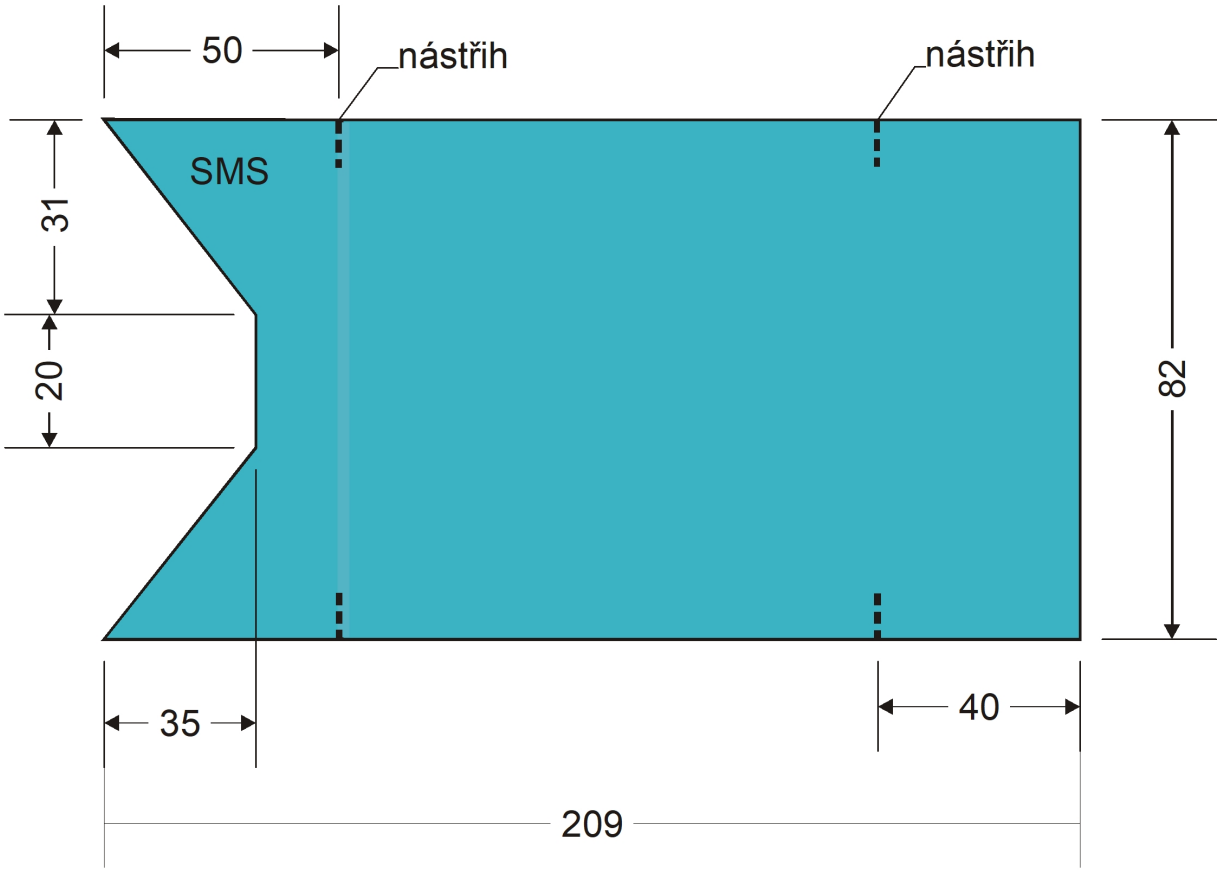


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DRAWING - DETAIL OF PRODUCT (DETAIL OF REINFORCEMENT, APERTURE, SIDE PANELS,...)

PRODUCT CODE: **PRODUCT DESCRIPTION:**

COS-502-055.-2S **Mayo cover SMS 209x82cm,sterile**



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FOLDING:

PRODUCT CODE: **PRODUCT DESCRIPTION:**

COS-502-055.-2S **Mayo cover SMS 209x82cm,sterile**

Folding Method: K

Width of Folded Product (cm):

Height of Folded Product (cm):

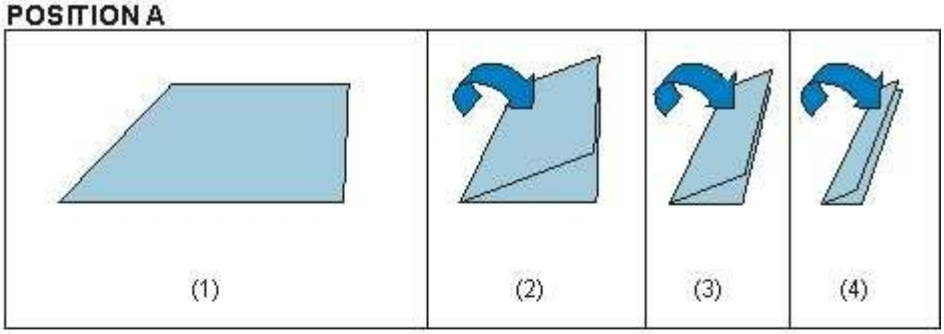
FOLDING ACCORDING TO THE METHOD BELOW OR DESCRIPTION IN THE DRAWING ABOVE:

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

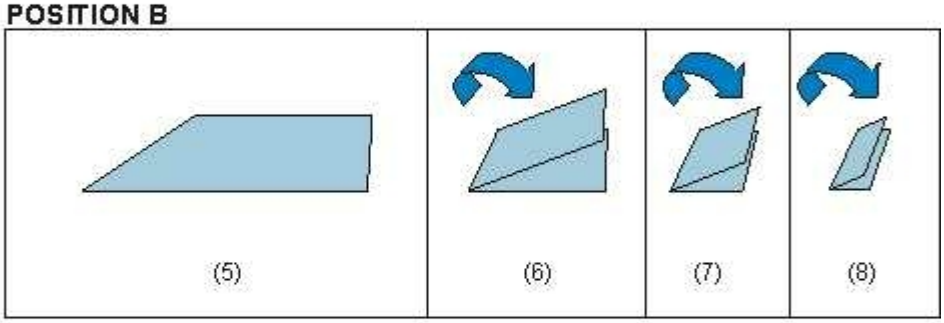
FOLDING TECHNIQUES

CLASSIC FOLDING TECHNIQUE [K]
(for simple drapes)

POSITION A



POSITION B



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