Date of printing: 08.11.2022

PRODUCT CODE: **PRODUCT DESCRIPTION:**

COS-20-0131.-2S **surgical drape DS2 40x60cm,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-20-0131.-2S **surgical drape DS2 40x60cm,sterile**

PACKAGING:

Case Quantity (Pcs): 150,00

Weight of Packaging (kg): 3,44

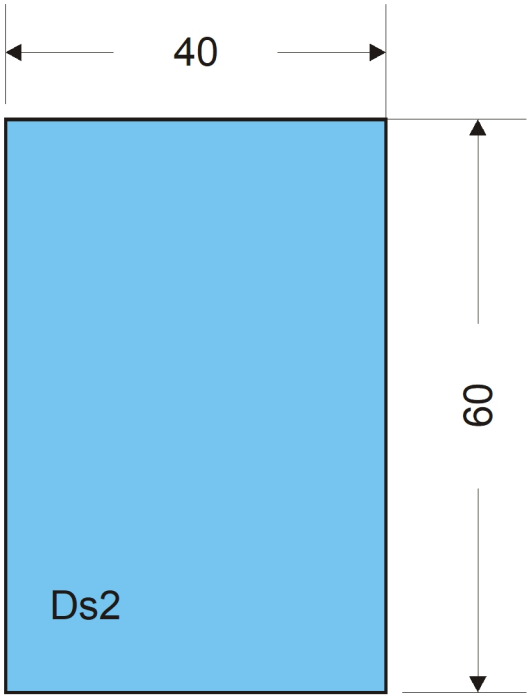
BILL OF MATERIAL:

Code:	Type:	Description of Item:	Size:		Unit:
P-20-0131	Semi Product:	Surgical drape DS2, 40x60 cm		1,000	pcs
DS2/DH-M-60	Raw material	two layer laminate DS2/DH, 60 cm, blue	60,00	40,000	cm
PEF-M-243/25	Raw material	PE foil, blue colour, the width 243cm, 25my, CARE 338		1,000	m
VIS-M-242/26	Raw material	Viscose, 242cm/28g, blue		1,000	m
LEP-003	Raw material	K MELT W-3500		0,002	k
SPE-10X10/30	Microtene Pouch:	PE pouch 10x10cm/50my		1,000	pcs
SPF-EO-15X28	Sterilization Pouch:	MM70-1/PP50-1 see-through-pouches 150 x 270		1,000	pcs
ERS-7X10/1	Label:	label in roll self-adhesive, 7x10 cm with 1 peel off field		1,000	pcs
KSB-VL5	Outer Box:	carton 39,3x33,8x26,5 cm, 5-layer, w/o printing, brown		1,000	pcs

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DRAWING:

PRODUCT CODE:	**PRODUCT DESCRIPTION:**
COS-20-0131.-2S	**surgical drape DS2 40x60cm,sterile**



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FOLDING:

PRODUCT CODE:	PRODUCT DESCRIPTION:
COS-20-0131.-2S	**surgical drape DS2 40x60cm,sterile**

Folding Method: HS1

Width of Folded Product (cm): 10,00

Height of Folded Product (cm): 7,00

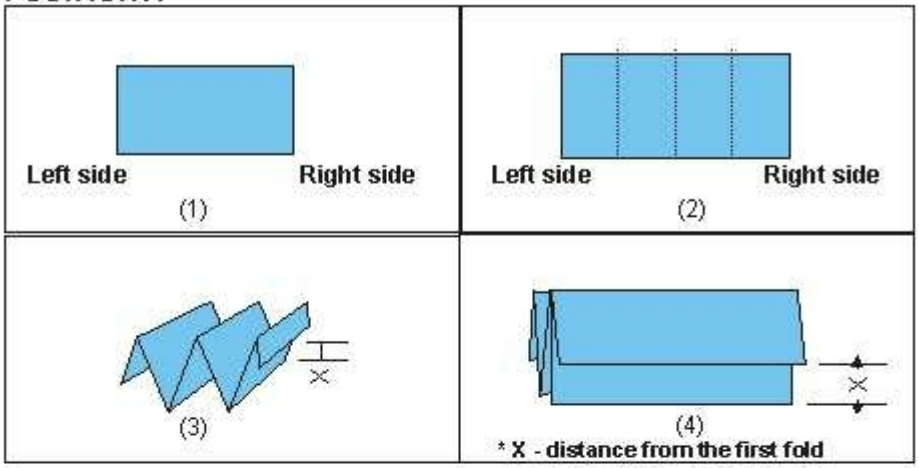
FOLDING ACCORDING TO THE METHOD BELOW OR DESCRIPTION IN THE DRAWING ABOVE:

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

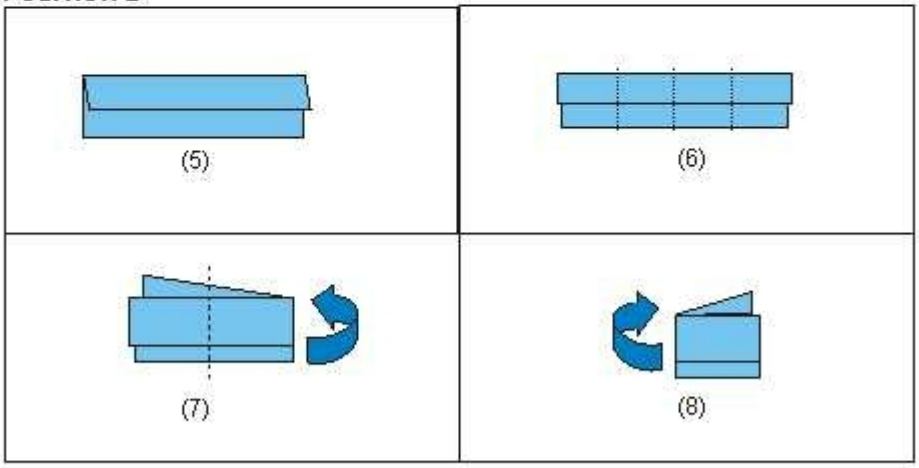
FOLDING TECHNIQUES

FOLDING TECHNIQUE HS1
(for automatic folding without adhesive tape)

POSITION A



POSITION B



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