EU DECLARATION OF CONFORMITY

Manufacturer: Toruńskie Zakłady Materiałów Opatrunkowych S.A. (TZMO SA)

Manufacturer address: ul. Żółkiewskiego 20/26, Toruń, 87-100, Poland

SRN number: PL-MF-000002200

Product name	Types/models	Version	BASIC UDI-DI code
Matodrape Drape	with opening, with cut-out, with slit, with pouch, under buttocks drape; 100x90, 113x90, 120x100, 130x80, 130x90, 150x75, 150x90, 160x120, 160x90, 170x90, 180x120, 180x150, 180x75, 200x130, 200x150, 200x180, 200x90, 210x160, 210x75, 210x80, 210x90, 220x90, 240x150, 240x180, 250x160, 250x90, 45x40, 45x45, 60x50, 72x50, 75x45, 80x45, 80x60, 90x60, 90x75, 90x80, 45x30	non sterile	5900516AAMXXXXV3

Risk class and classification rule: I/1

Product application : Products are designed for use after sterlisation as patient protection during a medical examination or a surgical proceeding in order to minimize the spread of infective agents to and from patients' operating wounds, thereby helping to prevent post-operative wound infections.

UMDNS code: 15646

Applied standards: PN-EN ISO 13485:2016; PN-EN ISO 62366-1:2015; PN-EN ISO 14971:2020 PN-EN ISO 15223-1:2017; PN EN ISO 1041+A1:2013; PN-EN ISO 10993-1:2010 PN-EN 13795-1:2019

We declare, under our sole responsibility, that the medical devices described in the declaration bearing the CE marking comply with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) as amended. The declaration has been drawn up on the basis of the requirements in Annex IV of this Regulation.
TZMO SA has a certified quality management system, in accordance with the requirements of the standards: ISO 9001:2015, certificate number PL008673/P (issued by Bureau Veritas Polska Sp. z o.o.) and ISO 13485:2016, certificate number 283504-2019-AQ-POL-FINAS (issued by DNV GL Business Assurance Finland Oy Ab).

Toruń, 20.05.2021

Tomasz Przybylski

Deputy Director for Production and Innovation, TZMO SA

acting as representative of Toruńskie Zakłady Materiałów Opatrunkowych S.A.

/qualified electronic signature/

Rafał Budzyński

Plenipotentiary of the President of the Management Board for Production and Innovation, TZMO SA

acting as representative of Toruńskie Zakłady Materiałów Opatrunkowych S.A.

/qualified electronic signature/

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TECHNICAL DATA SHEET
TDS - DRAPE - 01

DRAPES OF NONWOVEN, LAMINATE AND FILM, STERILE, NON STERILE

I. PRODUCT DESCRIPTION

Drapes are made of various types of nonwovens, laminates and films. They can have an opening and/ or an adhesive tape. Drapes used for draping the patient can be equipped with items needed for the given procedure (e.g. pouches, liquid pouches, cable organisers, integrated legs, incise films).

II. APPLICATION

The drapes comply with the EN 13795-1, however, the surface of the raw materials from the table - point: 1,3,4,5 meet standard and high requirements. However, the surface of the raw materials from point: 2,6,7 meet the standard requirements for the less critical product area. They are intended for use by medical personnel in operating theatres and outpatient rooms as a protective barrier during surgical procedures.

III. RAW MATERIALS

No.	raw material	parameter	value	test method/appendices
1.	PE film 42 µm	Thickness [µm]	≥ 60	PN-ISO 4593
		Breaking strength [MPa]	MD > 14.7	PN-C 89258-2
			CD > 10.8	PN-C 89258-2
2.	Polypropylene nonwoven SMS 35 g/m^2			TDS - APPENDIX - 03
3.	Polypropylene-polyethylene laminate TF 43 g/m^2			TDS - APPENDIX - 04
4.	Laminate BLUE COMFORT L3 73 g/m^2			TDS - APPENDIX - 05
5.	Laminate BLUE SPECIAL L2 56 g/m^2			TDS - APPENDIX - 06

6. Cellulose-polyethylene laminate FB FB 42 g/m²	TDS - APPENDIX - 07
7. Polypropylene-polyethylene laminate BTBS 27 g/m²	TDS - APPENDIX -13

IV. PRODUCT DIMENSIONS

Dimensions of drapes – they come in different shapes and sizes depending on their final use.

Drapes are available in the following versions:

- without an opening, without an adhesive tape,
- without an opening, with an adhesive tape along the edge (at the entire length or a part of it),
- with an opening and an adhesive tape,
- with an opening,
- with a few openings and adhesive tapes placed in different places of the drape
- with elements resulting from the procedure for which they are intended for (including bags, pouches, cable organisers, integrated legs, incise films, reinforcements made of, e.g. absorbent laminate, elastic elements)

V. SHELF LIFE

Product shelf life is 5 years from the date of manufacture.

VI. STERILISATION

Sterile drapes made of film coated nonwoven, laminates or films are sterilised with ethylene oxide. Drapes made of SMS nonwoven which do not have any adhesive tapes can be steam sterilised. Sterilisation processes are validated according to EN ISO 11135, EN ISO 17665-1.

VII. STORAGE, TRANSPORTATION

Storage and transportation conditions are as set out in appendix: Storage and transportation conditions for TZMO products.

VIII. STANDARDS

The products comply with the requirements of standards:

- EN ISO 2286-2 Rubber- or plastics-coated fabrics -- Determination of roll characteristics -- Part 2: Methods for determination of total mass per unit area, mass per unit area of coating and mass per unit area of substrate
- EN 29073-3 Methods of test for nonwovens. Methods of test for nonwovens. Determination of tensile strength and elongation;
- EDANA WSP 401.0.R3 Determination of delamination strength
- EN 13938-1 Textiles -- Bursting properties of fabrics -- Part 1: Hydraulic method for determination of bursting strength and bursting distension
- EN 20811 Textiles. Determination of resistance to water penetration. Hydrostatic pressure test
- EN ISO 9073-6 Textiles -- Test methods for nonwovens -- Part 6: Absorption
- EN ISO 9073-11 Textiles -- Test methods for nonwovens -- Part 11: Run-off
- EN ISO 11737-1 Sterilisation of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
- EN ISO 9073-10 Textiles -- Test methods for nonwovens -- Part 10: Lint and other particles generation in the dry state
- EN ISO 22612 Clothing for protection against infectious agents -- Test method for resistance to dry microbial penetration
- EN ISO 22610 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment -- Test method to determine the resistance to wet bacterial penetration
- EN ISO 6941 Textile fabrics -- Burning behaviour -- Measurement of flame spread properties of vertically oriented specimens
- EN ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitisation
- EN 1773 Textiles. Fabrics. Determination of width and length

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