

TECHNICAL DATA SHEET

TDS - SET - 02



MATOSSET

SPECIALIST/OPERATIVE SETS, STERILE

I. PRODUCT DESCRIPTION

Specialist/operative sets are a combination of sterile products of gauze, nonwoven, plastic, nonwoven/laminates, metal and other materials used during procedures in accordance with a given medical procedure.

II. APPLICATION

Sterile specialist/operative sets are designed for use during surgical and ambulatory procedures.

III. TECHNICAL PARAMETERS

A. PRODUCT CHARACTERISTICS

	Characteristic
Composition	Sets may consist of the following products: OP-drapes, covers, surgical clothing, surgical face masks, examination / surgical gloves, disposable surgical instruments and equipment, containers, sterile lubricants, sterile water, incise film, drapes with incise film, abdominal swabs, swabs, tampons, ribbon dressings, sponges, gauze, dressings, bandages, cotton wool and cotton-viscose wool, plasters, adhesive tapes, tapes, paddings, spatulas, sponge sticks for disinfection and cotton swabs for smear tests, pouches, bags, connection tubes, stopcocks, aspirators, catheters, disposable metal surgical instruments, auxiliary substances (washing – Octenilin, lubricants for catheterisation, sterile water, water with glycerine), Optomesh meshes, blades and scalpels, electrode cleaner, flannel blanket (for newborn), caps for newborn, dressings, specialist dressings and other elements.

Sets may be packed in:

Type of packaging

- soft blister packs
- rigid blister packs
- paper-film pouches
- TYVEK®-film pouches
- sets may have double packaging, may be wrapped in a drape or crepe paper.

The requirements for packaging materials are in accordance with PN-EN 868-5.

Sets have information about the product on the label or pre-printed paper used to seal blister packs. The labels for Matoset products are TAG type labels - a three-part or five-part label, where one part is the main adhesive label with complete information about the medical device, while the other two/four parts are small removable adhesive labels with information about the batch number, expiration date, product code and e-mail contact address with the manufacturer.

Marking

The Baby-Tag labels used on blister packs are two small adhesive labels containing information about the batch number, expiry date, product index and manufacturer's logo.

All the information on the labels and the pre-printed paper is consistent with the EN-ISO 15223-1.

B. RAW MATERIAL PARAMETERS

Set component	Dimensions and parameters of raw material in accordance with the given Appendix:
Nurses and surgeon caps	TDS – DRESS – 07 NURSES CAPS AND SURGEON CAPS
Surgical gown	TDS – DRESS – 01 SURGICAL GOWNS SP TDS – DRESS – 13 SURGICAL GOWNS HP
Surgical apron	TDS – DRESS – 04 SURGICAL APRONS
Procedure gown	TDS – DRESS – 02 PROCEDURE GOWNS
Procedure gown	TDS – DRESS – 03 STANDARD PROCEDURE GOWNS
Incise film	TDS – INCISE – 01 INCISE FILM
Film pouch	TDS – DRAPE – 07 POUCHES
Surgical clothing set	TDS – DRESS – 05 SURGICAL CLOTHING SETS
Absorbent swab	TDS – ABSORBA – 01 ABSORBENT SWAB

Nose swab	TDS – ABSORBA – 03 NOSE SWAB
Neurosurgical swab	TDS – NEURO – 01 NEUROSURGICAL SWABS
High-absorbent swab	TDS – ABSORBA – 02 HIGH-ABSORBENT SWAB
Gauze swab	TDS – COMP – 02 GAUZE SWABS WITH FOLDED EDGES / SETS OF GAUZE SWABS
Nonwoven swab	TDS – VLIES – 01 NONWOVEN SWABS
Dress	TDS – DRESS – 12 DELIVERY DRESS
Face masks	TDS – SMASK – 01 SURGICAL FACE MASKS
Matocell	TDS – CELL – 01 MATOCELL DENT
Matocell	TDS – CELL – 02 MATOCELL PAD
Matocell	TDS – CELL – 03 MATOCELL DENT
Surgical instrument	TDS – INSTRUMENT – 01 METAL SURGICAL INSTRUMENTS TDS – INSTRUMENT – 02 INSTRUMENTS, EQUIPMENT
Patient clothing	TDS – DRESS – 08 SHOE COVERS
Eye dressing	TDS – DRESS – 09 CLOTHING FOR PATIENTS
Eye dressing	TDS – ABSORBA – 04 EYE DRESSING
Dressing Medisorb A	TDS – MEDISORB – 01 MEDISORB A
Dressing Medisorb F	TDS – MEDISORB – 05 MEDISORB F
Dressing Medisorb G	TDS – MEDISORB – 02 MEDISORB G
Dressing Medisorb H	TDS – MEDISORB – 03 MEDISORB H
Dressing Medisorb P	TDS – MEDISORB – 04 MEDISORB P
Bandage Matoban	TDS – BAND – 10 MATOBAN
Bandage Matofix Cohesive	TDS – BAND – 06 MATOFIX COHESIVE
Bandage Matokrep Cohesive	TDS – BAND – 05 MATOKREP COHESIVE
Bandage Matolast	TDS – BAND – 07 MATOLAST
Bandage Matopat Ideal	TDS – BAND – 02 MATOPAT IDEAL
Bandage Matopat Standard	TDS – BAND – 01 MATOPAT STANDARD
Bandage Matopress	TDS – BAND – 03 MATOPRESS
Bandage Matopat Universal	TDS – BAND – 11 MATOPAT UNIVERSAL
Bandage Matovis	TDS – BAND – 12 MATOVIS
Medical device cover	TDS – DRAPE – 03 COVERS FOR MEDICAL DEVICES
Dressing Cannula F	TDS – PLAST – 06 CANNULA F
Dressing Cannula Plast	TDS – PLAST – 04 CANNULA PLAST
Dressing Fixopore S	TDS – PLAST – 03 FIXOPORE S
Dressing Fixopore	TDS – PLAST – 07 FIXOPORE
Dressing Fixopore F	TDS – PLAST – 10 FIXOPORE F
Plasters	TDS – PLAST – 02 PLASTERS
Dressing Fixovis	TDS - PLAST - 08 FIXOVIS

Gynaecological towel	TDS – ABSORGYN – 01 GYNAECOLOGICAL TOWELS
Natural orthopaedic padding	TDS – SOFT – 01 NATURAL ORTHOPAEDIC PADDING
Synthetic orthopaedic padding	TDS – SOFT – 02 SYNTHETIC ORTHOPAEDIC PADDING
Mayo table cover	TDS – DRAPE – 05 MAYO TABLE COVER
Nonwoven cover	TDS – DRAPE – 02 NONWOVEN COVERS
Nonwoven bedclothes	TDS – VKOMFORT – 01 NONWOVEN BEDCLOTHES
Pro Ophta	TDS – ELE – 001
Urine bags	TDS – ELE – 002
Adhesive tape Plastofilm	TDS – PRZYL – 01 PLASTOFILM
Adhesive tape Plastopore - Soft	TDS – PRZYL – 03 PLASTOPORE - SOFT
Adhesive tape Plastosilk	TDS – PRZYL – 04 PLASTOSILK
Adhesive tape Plastovis	TDS – PRZYL – 05 PLASTOVIS - CLASSIC
Glove	TDS – GLOVE – 01 SURGICAL GLOVES TDS – GLOVE – 02 EXAMINATION GLOVES
Instrument table cover	TDS – DRAPE – 06 INSTRUMENT TABLE COVER
Gauze abdominal swab	TDS – ABDOMA – 01 ABDOMINAL SWABS
Drapes of nonwoven, laminates, film	TDS – DRAPE – 01 DRAPES OF NONWOVEN, LAMINATES AND FILM
Gauze ribbon	TDS – SETON – 01 GAUZE ROLLS
Nonwoven ribbon	TDS – SETON – 02 NONWOVEN ROLLS
Surgical dress	TDS – DRESS – 11 SURGICAL DRESS
Tamponade dressing	TDS – ABSORBA – 05 PACKINGS
Cotton-wool and gauze tampon	TDS – ABSORBA – 06 COTTON-WOOL AND GAUZE TAMPON
Medical fixing tapes	TDS – DRAPE – 08 MEDICAL TAPES AND ORGANISERS
Nonwoven tunnel covers	TDS – DRAPE – 04 NONWOVEN TUNNEL COVERS
Gauze tampon	TDS – TUPFER – 01 GAUZE TAMPONS
Nonwoven tampon	TDS – TUPFER – 02 NONWOVEN TAMPONS
Pouch for organs	TDS – WOREK – 01 POUCHES FOR ORGANS
Sleeve protector	TDS – DRESS – 06 SLEEVE PROTECTORS

IV. SHELF LIFE

The product shelf life depends on the set composition. The product shelf life is 3 or 5 years from the date of manufacture. 3 years of validity is given for sets containing metal instruments, plasters, adhesive tapes, examination gloves (any type). 5 years of validity is given for sets containing other items without their own packaging. For Matoset sets containing elements previously sterilised in their own individual packaging the

validity period is the equivalent of the expiration date on the own packaging of this item, but not longer than 5 years.

V. STERILISATION

The specialist/operative sets are sterilised with steam or ethylene oxide, depending on the contents of the set.

Sterilisation processes validated according to PN-EN ISO 17665-1, PN-EN ISO 11135.

VI. STORAGE AND TRANSPORTATION

Storage and transportation conditions are as set out in appendix [Storage and transportation conditions for TZMO products](#).

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