

## microscope slides

### non-sterile

#### features

- made of high-quality transparent glass
- smooth surface
- dimensions meet international standards
- flat, even and durable surface
- even specimens, good staining of preparations
- box wrapped in foil for additional protection against humidity
- dimensions: 76 mm x 26 mm x 1 mm
- non-sterile
- packaging: 50 pcs/double packaging: box and foil

#### indication

- designed for holding specimens for microscopic study

REF	version	intermediate packaging
SP-01	unground edges	50 pcs
SP-11	ground edges with frosted description field	50 pcs



bulk packaging:  
50 x 50 pcs



## entrance mat

### non-sterile

#### features

- blue mat consisting of 30 layers - thin sticky sheets
- each of the sticky sheets made of polyethylene resin
- does not contain heavy metals
- excellent adhesive properties
- the first and last sheets secured with a non-adhesive foil
- low mat profile: app. 2 mm thick
- the bottom surface adheres very well to the floor over the entire surface, preventing adverse movement of the mat, allowing trouble-free passage of trolleys with equipment or beds, without the risk of curling up the mat or tearing
- no need to clean the mat - as soon as the surface of the mat is contaminated, it should be torn off to uncover a new, clean sheet
- there is numbering of sheets on a white non-adhesive material in the mat corner facilitate quick identification and easy removal of subsequent sheets
- light, easy to spread
- non-sterile

#### indication

- preventing spreading of contamination brought on shoe soles and wheelchairs to operating rooms

REF	dimensions	intermediate packaging
M001	45 cm x 115 cm	10 pcs




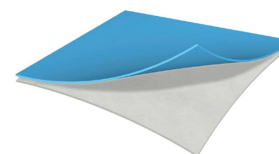
bulk packaging:  
5 x 10 pcs



## SURGICAL DRAPE 2-LAYER DRAPE


### STERILE DRAPE WITH CELLULOSE LAYER - 2-LAYERED

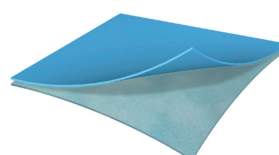
ref.	dimensions	packaging unit	 bulk packaging
AT-PF-S 1	50cm x 50cm	1 pc.	700 pcs
AT-PF-S 3	50cm x 70cm	1 pc.	450 pcs
AT-PF-S 5	80cm x 80cm	1 pc.	200 pcs
AT-PF-S 6	75cm x 90cm	1 pc.	250 pcs
AT-PF-S 8	90cm x 150cm	1 pc.	125 pcs



135


### STERILE SURGICAL DRAPE - 2-LAYERED

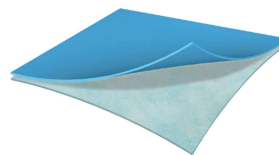
ref.	dimensions	packaging unit	 bulk packaging
AT-NF-S 21 E	37cm x 45cm	100 pcs	4 x 100 pcs
AT-NF-S 1 E	45cm x 45cm	100 pcs	4 x 100 pcs
AT-NF-S 3 E	45cm x 60cm	100 pcs	4 x 100 pcs
AT-NF-S 4 E	45cm x 75cm	100 pcs	4 x 100 pcs
AT-NF-S 5 E	75cm x 75cm	50 pcs	4 x 50 pcs
AT-NF-S 9 E	75cm x 90cm	50 pcs	4 x 50 pcs
AT-NF-S 13 E	100cm x 150cm	50 pcs	4 x 50 pcs
AT-NF-S 15 E	150cm x 180cm	20 pcs	4 x 20 pcs




  
economic  
version

### STERILE SURGICAL DRAPE - 2-LAYERED

ref.	dimensions	packaging unit	 bulk packaging
AT-NF-S 1	45cm x 45cm	1 pc.	240 pcs
AT-NF-S 2	50cm x 50cm	1 pc.	200 pcs
AT-NF-S 3	50cm x 60cm	1 pc.	280 pcs
AT-NF-S 4	50cm x 70cm	1 pc.	160 pcs
AT-NF-S 5	75cm x 75cm	1 pc.	150 pcs
AT-NF-S 9	75cm x 90cm	1 pc.	150 pcs
AT-NF-S 10	90cm x 120cm	1 pc.	80 pcs
AT-NF-S 13	100cm x 150cm	1 pc.	50 pcs
AT-NF-S 14	120cm x 150cm	1 pc.	50 pcs
AT-NF-S 15	150cm x 180cm	1 pc.	20 pcs
AT-NF-S 16	150cm x 200cm	1 pc.	20 pcs
AT-NF-S 17	180cm x 180cm	1 pc.	20 pcs
AT-NF-S 20	150cm x 240cm	1 pc.	20 pcs
AT-NF-S 22	170cm x 300cm	1 pc.	20 pcs



### STERILE SURGICAL DRAPE WITH ADHESIVE EDGE - 2-LAYERED

ref.	dimensions	packaging unit	 bulk packaging
AT-NFA-S 1 E	45cm x 45cm	100 pcs	4 x 100 pcs
AT-NFA-S 4 E	45cm x 75cm	100 pcs	4 x 100 pcs
AT-NFA-S 9 E	75cm x 90cm	50 pcs	4 x 50 pcs
AT-NFA-S 10 E	90cm x 120cm	50 pcs	4 x 50 pcs
AT-NFA-S 13 E	90cm x 150cm	50 pcs	4 x 50 pcs
AT-NFA-S 15 E	150cm x 175cm	20 pcs	4 x 20 pcs
AT-NFA-S 16 E	150cm x 200cm	20 pcs	4 x 20 pcs
AT-NFA-S 20 E	150cm x 240cm	20 pcs	4 x 20 pcs



  
adhesive tape  
on the longer  
side of drape

  
economic  
version

# dispoSULIN

## insulin pen needle, sterile

### features

- made of polypropylene, polyethylene and stainless steel
- triple-point needle blade allows easy and atraumatic skin penetration
- covering the needle with silicone lubricant reduces resistance during injection
- thin walls of needle ensure easy flow of medicine and the right flow rate
- coloured cap and paper cover of packaging make it easy to quickly recognize size of needle
- available in various sizes, allowing you to adapt to individual needs
- universal, compatible with all pen models
- single-use
- non-pyrogenic, non-toxic
- latex-free, phthalate-free
- EO sterilized
- packaging: 100 pcs/box

### indication

- for subcutaneous injection
- dedicated for use with pre-filled pens (insulin pens)

REF	size	colour	G	intermediate packaging
INP-033X12	0,33 mm x 12 mm	pink	29	100 pcs
INP-030X08	0,30 mm x 8 mm	yellow	30	100 pcs
INP-025X06	0,25 mm x 6 mm	purple	31	100 pcs
INP-025X08	0,25 mm x 8 mm	blue	31	100 pcs



bulk packaging:  
50 x 100 pcs



**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60139535 0001

**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

**Products:** (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60117020 0001

**Expiry Date:** 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2019-06-09

**Date:** 2019-05-27

**Notified Body**

Rafal Byczkowski



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/6, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60139535 0001  
**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

**Products included:**

- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs  
(with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges  
(with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls  
(with or without X-ray thread)
- Sterile and non-sterile gauze rolls  
(with or without X-ray thread)
- Sterile and non-sterile non-woven swabs  
(with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump

**Notified Body**

**Date: 2019-05-27**

  
**Rafal Byczkowski**





**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/6, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60139535 0001  
**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

**Products included:**

- Sterile endotracheal tubes
- Sterile tracheostomy tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Multi-Vent masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizer sets
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use

**Date: 2019-05-27**

**Notified Body**

**Rafal Byczkowski**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 3/6, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60139535 0001  
**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczoną odpowiedzialnością,  
spółka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

**Products included:**

- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles
- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves

**Notified Body**

**Date: 2019-05-27**

  
**Rafal Byczkowski**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 4/6, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60139535 0001  
**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

**Products included:**

For the following medical devices the scope covers  
only the aspects of manufacture concerned with  
securing and maintaining sterile conditions:

- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes
- Fluid collection pouches
- Nelaton catheters

**Notified Body**

**Date: 2019-05-27**

  
**Rafal Byczkowski**





**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 5/6, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60139535 0001  
**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

**Products included:**

For the following medical devices the scope covers  
only the aspects of manufacture concerned with  
securing and maintaining sterile conditions:

- Vaginal speculums
- Cervical brushes
- Urine bags
- Tongue depressors
- Guedel airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Alginate dressings
- Cannula stoppers
- Umbilical cord clamps

**Date: 2019-05-27**

**Notified Body**

  
**Rafal Byczkowski**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 6/6, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60139535 0001  
**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

**Products included:**

ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Gustawa Eiffel'a 15  
44-109 Gliwice  
Poland

**Activity:** Production

**Notified Body**

**Date:** 2019-05-27

  
**Rafal Byczkowski**



# Certificate

**Quality Management System**  
**EN ISO 13485:2016**



Registration No.: SX 1023663-1

Organization: ZARYS International Group  
Spółka z ograniczoną odpowiedzialnością,  
spółka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Poland

Scope: Design and development, manufacture and distribution of sterile:  
surgical kits, procedure sets, surgical drapes and sets of surgical  
drapes.  
Manufacture and distribution of sterile and non-sterile disposable  
medical devices and non-sterile reusable medical devices.  
Distribution of in-vitro medical devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the above mentioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84947434 020

Effective date: 2020-06-10

Expiry date: 2023-06-08

Issue date: 2020-06-10



Rafał Byczkowski  
TR LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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