

STERILE ABSORBENT DRAPE

ref.	dimensions	packaging unit
AT-HT	40cm x 40cm	1 pc.



bulk packaging:
500 pcs



made of cellulose



40x40cm

147

STERILE INCISE FILM elastoFILM

ref.	total dimensions	adhesive filed dimensions	packaging unit	bulk packaging
808067	56cm x 84cm	56cm x 78cm	1 pc.	6 pcs
808066	40cm x 42cm	40cm x 36cm	1 pc.	20 pcs
808065	45cm x 55cm	45cm x 49cm	1 pc.	20 pcs
808064	45cm x 28cm	45cm x 22cm	1 pc.	20 pcs
808063	30cm x 28cm	30cm x 22cm	1 pc.	20 pcs
808062	15cm x 28cm	15cm x 22cm	1 pc.	40 pcs
808061	14cm x 25cm	14cm x 21cm	1 pc.	40 pcs
805018	55cm x 55cm	55cm x 51cm	1 pc.	20 pcs
805025	30cm x 40cm	30cm x 36cm	1 pc.	20 pcs
805016	20cm x 30cm	20cm x 26cm	1 pc.	30 pcs



do not cut
the incise film



- thin incise film made of polyurethane
- flexible
- perfectly fits the patient's body
- double packed: externally paper-foil, internally paper



CELLULOSE

Cellulose is a solid with typically fiber structure. Two-step process is used for industrial manufacturing of cellulose fibers, which was developed in 1892. Cellulose raw material is used in different industries as textiles and paper as well as in production of explosives.

surgical suction set

with Yankauer cannula, standard, sterile

CANNULA

- completely transparent for full possibility of observing the sucked secretion
- light and perfectly balanced handle ensures high comfort of work and reduces hand fatigue
- perfectly smooth inner surface prevents blocking or retaining the sucked content, ensuring correct and optimal flow
- cannula with double bend of curvature
- four lateral eyes, which prevent the tip from sticking to the tissues and one central opening
- universal stepped connector ensures tight connection with a wide range of suction connecting tubes

TUBE

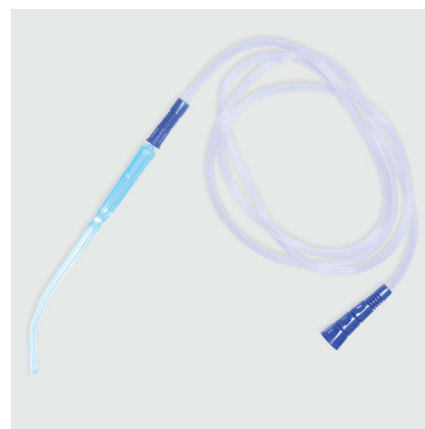
- made of soft and flexible PVC
- along the tube a special longitudinal reinforcement to prevent bending and sucking of the tube
- perfectly smooth inner surface of tube prevents the sucked content from settling on the walls, ensuring correct and optimal flow
- connector type funnel-funnel cut-to-fit with the possibility of cutting in the marked places of the connector and matching to any type of medical suction device (for the diameter of 8 mm to 18 mm)
- funnel connector equipped with a special bending system, enabling convenient manipulation of the tube
- tube connectors compatible with the standard suction cannulas, enabling their reliable, effective and tight connection

features

- available with or without suction control
- single-use
- latex-free
- EO sterilized
- packaging: 1 set/double packaging: internal- foil, external- paper-foil

indication

- evacuating secretions and body fluids from the operating field in general surgery



REF	size of cannula/ size of tube	length of tube	version
ZO-212400104	CH 21 / CH 24	210 cm	without suction control, funnel-funnel
ZO-212400114	CH 21 / CH 24	210 cm	with suction control, funnel-funnel
ZO-402423104	CH 21 / CH 24	400 cm	without suction control, funnel-funnel
ZO-402423114	CH 21 / CH 24	400 cm	with suction control, funnel-funnel
ZO-2124001041	CH 21 / CH 24	210 cm	without suction control, funnel-funnel cut-to-fit
ZO-2124001141	CH 21 / CH 24	210 cm	with suction control, funnel-funnel cut-to-fit



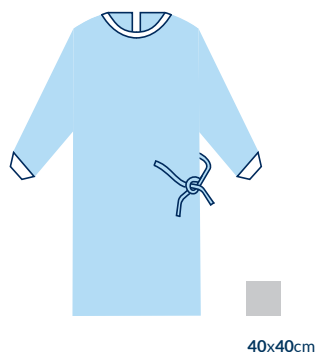
bulk packaging:
50 x 1 set

STERILE GOWN NORMAL - 22

ref.	size	trimming	packaging unit
AT-SGN-L	L		1 pc.
AT-SGN-XL	XL		1 pc.

 bulk packaging:
25 pcs

 includes
1 absorbent towel
40cm x 40cm




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STERILE SURGICAL GOWN STANDARD - 35

ref.	size	trimming	packaging unit
AT-SGS-M 1	M		1 pc.
AT-SGS-L 1	L		1 pc.
AT-SGS-XL 1	XL		1 pc.
AT-SGS-XXL 1	XXL		1 pc.

 bulk packaging:
25 pcs

 includes
2 absorbent towels
30cm x 30cm

 also available without
wrapping and
absorbent towels

 **BESTSELLER**



STERILE SURGICAL GOWN STANDARD - 45





ref.	size	trimming	packaging unit
AT-SGS-M	M		1 pc.
AT-SGS-L	L		1 pc.
AT-SGS-XL	XL		1 pc.
AT-SGS-XXL	XXL		1 pc.

 bulk packaging:
25 pcs

 includes
2 absorbent towels
30cm x 30cm




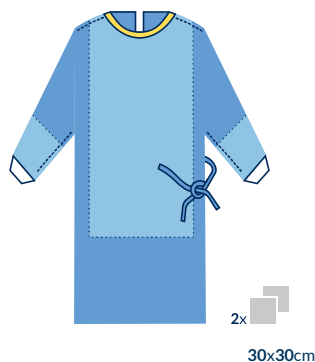
STERILE SURGICAL GOWN STANDARD PLUS - 35

ref.	size	trimming	packaging unit
AT-SGSP-M 1	M		1 pc.
AT-SGSP-L 1	L		1 pc.
AT-SGSP-XL 1	XL		1 pc.
AT-SGSP-XXL 1	XXL		1 pc.

 bulk packaging:
25 pcs

 includes
2 absorbent towels
30cm x 30cm

 also available without
wrapping and
absorbent towels



easyFLOW IS



infusion set, sterile

features

- 2-way sharp closure-piercing device of the drip chamber with anti-slip surface that guarantees tight and reliable connection with fluid containers/bags
- air inlet with anti-bacterial filter and coloured (blue) flap
- pliable drip chamber, size 6 cm, equipped with additional pressure wings to facilitate insertion into containers with liquids
- dropper: 20 drops = 1 ml +/- 0,1 ml
- fluid filter protecting against larger particles with pore size 15 µm
- min. 150 cm-long, soft, flexible tubing with luer lock conical fitting
- precise safe flow regulator with integrated holder for the closure-piercing device and with hook for securing the tubing
- name of the manufacturer placed on the flow regulator
- both tips of the device additionally secured with protective caps
- device available in a version containing phthalates and without phthalates
- single-use
- non-pyrogenic, non-toxic
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil with a coloured code (blue) identifying the device

indication

- device for fluid transfer in infusion therapy

REF	version		
IS	with phthalates	<div>  bulk packaging: 250 pcs </div>	<div>  BESTSELLER </div>
IS-BF	without phthalates		



extension tube for infusion pump


sterile

features

- tubing made of PVC
- device available in a transparent and amber version for photosensitive medicines
- diameter of the tubing - outer: 2,4 mm; inner: 1,24 mm
- luer lock fitting - male and female
- single-use
- latex-free, phthalate-free
- non-pyrogenic, non-toxic
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- device used to extend infusion line

REF	colour of tube	length	intermediate packaging	
P450-BF	transparent	45 cm	50 pcs	<div>  bulk packaging: 24 x 50 pcs </div>
P1500-BF	transparent	150 cm	50 pcs	
PB1500-BF	amber	150 cm	50 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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