

ADHESIVE TAPES

features

- flexible, conforms to the body's contours, guarantees freedom of movement
- characterized by adequate air and water vapour permeability
- good adhesion
- can be divided lengthwise and widthwise without the use of scissors
- hypoallergenic

indication

- stabilization, protection and fixation of primary, non-adhesive dressings, applied directly to wounds and skin damages
- stabilization, protection and fixation of drains, catheters, medical tubes that do not require specialized fixing in the place of their insertion



adhesive fabric tape, white

SENSIplast



REF	dimensions	packaging unit box	bulk packaging carton
STA12505W	1,25 cm x 5 m	24 pcs	30 x 24 pcs
STA25005W	2,5 cm x 5 m	12 pcs	30 x 12 pcs
STA50005W	5 cm x 5 m	6 pcs	30 x 6 pcs
STA12509W	1,25 cm x 9,14 m	24 pcs	30 x 24 pcs
STA25009W	2,5 cm x 9,14 m	12 pcs	30 x 12 pcs
STA50009W	5 cm x 9,14 m	6 pcs	30 x 6 pcs



adhesive fabric tape, beige colour

PLASTIplast



REF	dimensions	packaging unit box	bulk packaging carton
SZO12505S	1,25 cm x 5 m	24 pcs	30 x 24 pcs
SZO25005S	2,5 cm x 5 m	12 pcs	30 x 12 pcs
SZO50005S	5 cm x 5 m	6 pcs	30 x 6 pcs



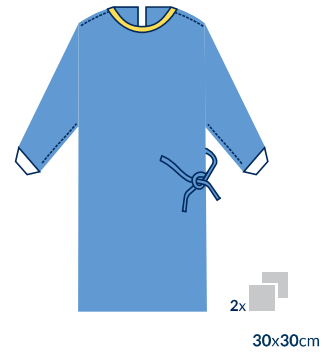
STERILE SURGICAL GOWN STANDARD

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


45 g/m²



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STERILE SURGICAL GOWN SOFT

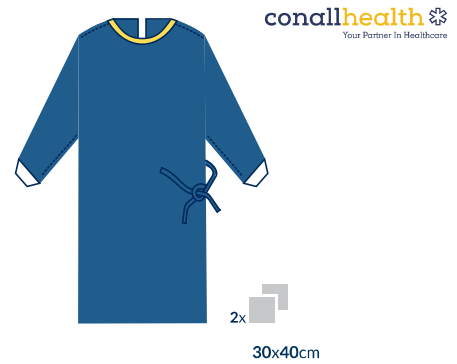
ref.	size	trimming	packaging unit
35SSG-M	M		1 pc.
35SSG-L	L		1 pc.
35SSG-XL	XL		1 pc.
35SSG-XXL	XXL		1 pc.


bulk packaging:
50 pcs


includes
2 absorbent towels
30cm x 40cm


soft SMS
material


35 g/m²



STERILE SURGICAL GOWN STANDARD PLUS

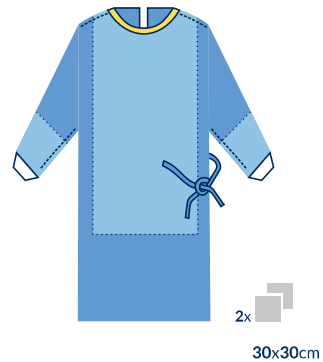
ref.	size	trimming	packaging unit
AT-SGSP-M 1	M		1 pc.
AT-SGSP-L 1	L		1 pc.
AT-SGSP-XL 1	XL		1 pc.
AT-SGSP-XXL 1	XXL		1 pc.
AT-SGSP-XXXL 1	XXXL		1 pc.


bulk packaging:
25 pcs


includes
2 absorbent towels
30cm x 30cm


35 g/m²


BESTSELLER



STERILE SURGICAL GOWN STANDARD PLUS

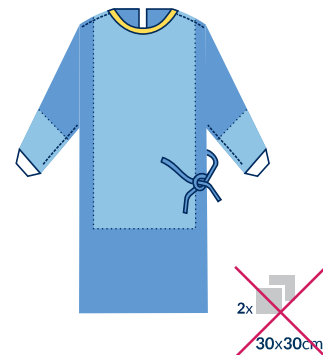
ref.	size	trimming	packaging unit
AT-SGSP-M 1E	M		1 pc.
AT-SGSP-L 1E	L		1 pc.
AT-SGSP-XL 1E	XL		1 pc.
AT-SGSP-XXL 1E	XXL		1 pc.


bulk packaging:
25 pcs


without
2 absorbent towels
30cm x 30cm


economic
version


35 g/m²



SELF-ADHESIVE DRESSINGS WITH ABSORBENT PAD

features

- self-adhesive dressings with centrally situated absorbent pad, made of hydrophobic non-woven, covered with acrylic glue
- absorbent pad coated with a polyethylene mesh that prevents sticking to the wound, absorbs a small and medium amount of exudate and protects against the influence of external factors
- rounded edges prevent accidental removal of the dressing
- silicone backing paper facilitates the precise, painless and efficient application
- micropores in the structure of the non-woven provide adequate vapor permeability, thanks to which a proper gas exchange between the dressing and the skin takes place
- hypoallergenic

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non-woven dressing with absorbent pad

elastopor STERIL



indication

- especially recommended for covering surgical wounds
- for treating wounds with a small and medium amount of exudate

REF	dimensions	packaging unit paper-paper	bulk packaging box
801001	5 cm x 7,2 cm	1 pc.	100 x 1 pc.
801012	6 cm x 10 cm	1 pc.	50 x 1 pc.
801002	8 cm x 10 cm	1 pc.	30 x 1 pc.
801013	10 cm x 10 cm	1 pc.	30 x 1 pc.
801021	10 cm x 12 cm	1 pc.	30 x 1 pc.
801014	10 cm x 15 cm	1 pc.	30 x 1 pc.
801003	6 cm x 15 cm	1 pc.	50 x 1 pc.
801004	8 cm x 15 cm	1 pc.	30 x 1 pc.
801005	8 cm x 20 cm	1 pc.	30 x 1 pc.
801015	10 cm x 20 cm	1 pc.	25 x 1 pc.
801016	10 cm x 25 cm	1 pc.	25 x 1 pc.
801017	10 cm x 30 cm	1 pc.	25 x 1 pc.
801018	10 cm x 35 cm	1 pc.	25 x 1 pc.



non-woven IV cannula dressing

elastopor IV



features

- centrally situated absorbent pad protects the non-woven material from sticking to the injection site
- non-woven lining should be placed under cannula's wings, which prevents it from causing damage to the skin

indication

- dressing application around the inserted cannula
- stabilization, protection and fixation of intravenous cannulas

REF	dimensions	packaging unit paper-paper	bulk packaging box
811013	6 cm x 8 cm	1 pc.	100 x 1 pc.
811012	5,1 cm x 7,6 cm	1 pc.	100 x 1 pc.
811023	6 cm x 8 cm	1 pc.	50 x 1 pc.
811022	5,1 cm x 7,6 cm	1 pc.	50 x 1 pc.

dicoNEX

single-use syringe, 3-part, luer, sterile

features

- transparent barrel allows full visual control of content
- green contrasting plunger
- luer nozzle
- sealing in the form of double ring on plunger stopper situated on the top of plunger
- smooth plunger sliding thanks to rubber sealing
- limitation flange securing against accidental removal of plunger
- special design of the 1 ml syringe plunger stopper reduces dead space
- name of syringe and manufacturer's logo placed on barrel
- clear, legible and permanent black graduation facilitating dosage, adequately:
 - every 0,01ml for capacity of 1ml
 - every 0,1 ml for capacity of 2 ml
 - every 0,2 ml for capacity of 5 ml
 - every 0,2 ml for capacity of 10 ml
 - every 0,5 ml for capacity of 20 ml
 - every 1 ml for capacity of 50/60 ml
- single-use, non-pyrogenic, non-toxic
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- 3-piece syringe intended for drawing up and administering of medicines/liquids to patient and collecting body fluid samples from patient

REF	type	capacity	position of nozzle	intermediate packaging	bulk packaging
001ML-3CZ-BL	luer	1 ml	centric	100 pcs	32 x 100 pcs
002ML-3CZ-BL	luer	2 ml	centric	100 pcs	30 x 100 pcs
005ML-3CZ-BL	luer	5 ml	centric	100 pcs	24 x 100 pcs
010ML-3CZ-BL	luer	10 ml	centric	100 pcs	16 x 100 pcs
020ML-3CZ-BL	luer	20 ml	eccentric	50 pcs	16 x 50 pcs
050ML-3CZ-BL	luer	50/60 ml	eccentric	25 pcs	16 x 25 pcs



dicoNEX

single-use syringe, 3-part, luer lock, sterile

features

- transparent barrel allows full visual control of content
- green contrasting plunger (amber-coloured syringe - white contrasting plunger)
- luer lock nozzle
- sealing in the form of double ring on plunger stopper situated on the top of plunger
- smooth plunger sliding thanks to rubber sealing
- limitation flange securing against accidental removal of plunger
- name of syringe and manufacturer's logo placed on barrel
- clear, legible and permanent black graduation facilitating dosage, adequately:
 - every 0,1 ml for capacity of 2 ml
 - every 0,2 ml for capacity of 5 ml and of 10 ml
 - every 0,5 ml for capacity of 20 ml
 - every 1 ml for capacity of 30 ml and of 50/60 ml
- single-use
- non-pyrogenic, non-toxic
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- 3-piece syringe intended for drawing up and administering of medicines/liquids to patient and collecting body fluid samples from patient
- amber-coloured syringe is intended for drawing up and administering of photosensitive medicines

REF	type	capacity	position of nozzle	colour of plunger	intermediate packaging	bulk packaging
003ML-3CZ-LL-BL	luer lock	3 ml	centric	green	100 pcs	30 x 100 pcs
005ML-3CZ-LL-BL	luer lock	5 ml	centric	green	100 pcs	24 x 100 pcs
010ML-3CZ-LL-BL	luer lock	10 ml	centric	green	100 pcs	16 x 100 pcs
020ML-3CZ-LL-BL	luer lock	20 ml	centric	green	50 pcs	16 x 50 pcs
030ML-3CZ-LL-BL	luer lock	30 ml	centric	green	50 pcs	16 x 50 pcs
050ML-3CZ-LL-BL	luer lock	50/60 ml	centric	green	25 pcs	16 x 25 pcs

amber type

050ML-3CZ-LL-B-BL	luer lock	50/60 ml	centric	white	25 pcs	16 x 25 pcs
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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

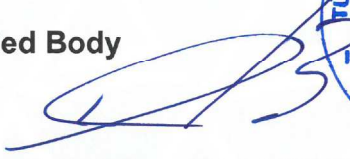
Products included:

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



Rafal Byczkowski



Date: 2019-05-27

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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