

## BEN medical cap with ties

### features:

- forage cap with ties at the back
- made of perforated Spunlace Mesh non-woven
- excellent breathability and comfort of use
- single-use, non-sterile

REF	packaging unit
BT-007-35B-SPNM	100 pcs



bulk packaging:  
10 x 100 pcs



available colours:



## TOM medical cap with ties

### features:

- cap with ties at the back
- anti-sweat insert on the whole circumference
- made of polypropylene non-woven 20 g/m<sup>2</sup>
- packaging: ergonomic cardboard box to remove individual pieces
- single-use, non-sterile

REF	packaging unit
BT-007-P20G	100 pcs



bulk packaging:  
10 x 100 pcs



anti-sweat  
insert



available colours:



## ROS medical cap with ties

### features:

- cap with ties at the back
- anti-sweat insert in the forehead area
- made of Spunlace and polypropylene non-woven
- packaging: ergonomic cardboard box to remove individual pieces
- latex-free
- single-use, non-sterile

REF	packaging unit
BT-007-P45B	50 pcs



bulk packaging:  
6 x 50 pcs



anti-sweat  
insert



available colours:



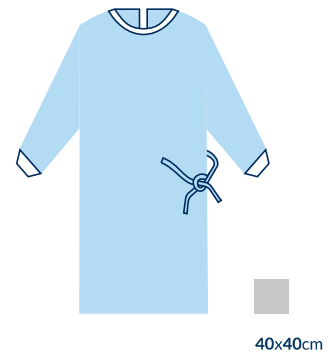
### STERILE GOWN NORMAL

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

22 g/m<sup>2</sup>



40x40cm

### STERILE SURGICAL GOWN STANDARD

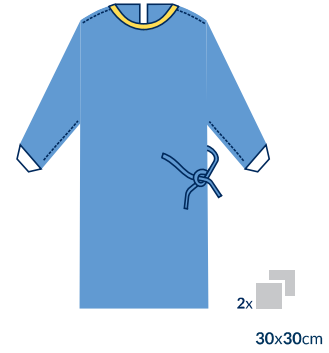
ref.	size	trimming	packaging unit
AT-SGS-M 1	M		1 pc.
AT-SGS-L 1	L		1 pc.
AT-SGS-XL 1	XL		1 pc.
AT-SGS-XXL 1	XXL		1 pc.
AT-SGS-XXXL 1	XXXL		1 pc.

bulk packaging:  
25 pcs

includes  
**2 absorbent towels**  
30cm x 30cm

35 g/m<sup>2</sup>

**BESTSELLER**



2x 30x30cm

### STERILE SURGICAL GOWN STANDARD

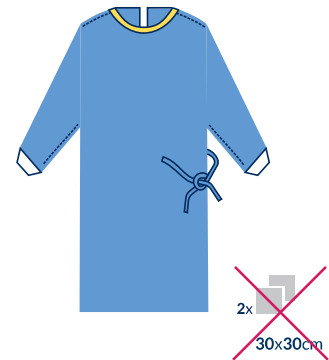
ref.	size	trimming	packaging unit
AT-SGS-M 1E	M		1 pc.
AT-SGS-L 1E	L		1 pc.
AT-SGS-XL 1E	XL		1 pc.
AT-SGS-XXL 1E	XXL		1 pc.

bulk packaging:  
25 pcs

without  
**2 absorbent towels**  
30cm x 30cm

economic version

35 g/m<sup>2</sup>



2x ~~30x30cm~~

### STERILE SURGICAL GOWN STANDARD

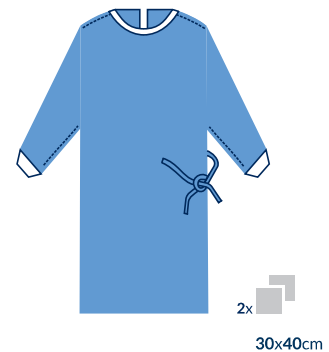
ref.	size	trimming	packaging unit
AT-SGS-M 1A	M		1 pc.
AT-SGS-L 1A	L		1 pc.
AT-SGS-XL 1A	XL		1 pc.
AT-SGS-XXL 1A	XXL		1 pc.

bulk packaging:  
50 pcs

includes  
**2 absorbent towels**  
30cm x 40cm

without colorful trimming

35 g/m<sup>2</sup>



2x 30x40cm

**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**



**Rafal Byczkowski**



**Date: 2019-05-27**

**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**

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spolka 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

**Date:** 2019-05-27

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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

  
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**TÜV Rheinland**  
**LGA Products GmbH**  
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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

Notified Body



**Date: 2019-05-27**

**Rafal Byczkowski**



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

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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

**Date: 2019-05-27**

**Notified Body**

**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