



STERILE SURGICAL DRAPES WITH ADHESIVE EDGE - 2-LAYERED

ref.	dimensions	packaging unit	 bulk packaging
AT-NFA-S 1	45cm x 45cm	1 pc.	2 x 230 pcs
AT-NFA-S 2	50cm x 50cm	1 pc.	2 x 200 pcs
AT-NFA-S 3	50cm x 60cm	1 pc.	2 x 100 pcs
AT-NFA-S 4	50cm x 70cm	1 pc.	2 x 210 pcs
AT-NFA-S 5	75cm x 75cm	1 pc.	2 x 135 pcs
AT-NFA-S 9	75cm x 90cm	1 pc.	2 x 125 pcs
AT-NFA-S 10	90cm x 120cm	1 pc.	2 x 80 pcs
AT-NFA-S 13	100cm x 150cm	1 pc.	2 x 50 pcs
AT-NFA-S 15	150cm x 180cm	1 pc.	2 x 20 pcs
AT-NFA-S 16	150cm x 200cm	1 pc.	2 x 20 pcs
AT-NFA-S 20	150cm x 240cm	1 pc.	2 x 20 pcs
AT-NFA-S 22	170cm x 300cm	1 pc.	2 x 20 pcs

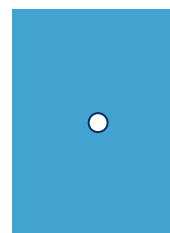



adhesive tape
on the longer
side of drape


60 g/m²

STERILE SURGICAL DRAPES WITH CENTRAL FENESTRATION - 2-LAYERED


ref.	dimensions	fenestration	packaging unit	 bulk packaging
AT-NFF-S 2 E	45cm x 75cm	6cm x 8cm	100 pcs	4 x 100 pcs
AT-NFF-S 3 E	45cm x 60cm	ø 6cm	100 pcs	4 x 100 pcs
AT-NFF-S 4 E	75cm x 90cm	ø 7cm	50 pcs	4 x 50 pcs
AT-NFF-S 5 E	75cm x 90cm	6cm x 8cm	50 pcs	4 x 50 pcs

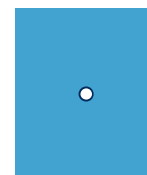



economic
version


40 g/m²


STERILE SURGICAL DRAPES WITH CENTRAL FENESTRATION - 2-LAYERED

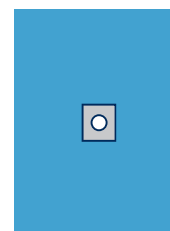
ref.	dimensions	fenestration	packaging unit	 bulk packaging
AT-NFF-S 1	45cm x 45cm	ø 6cm	1 pc.	2 x 200 pcs
AT-NFF-S 2	50cm x 75cm	6cm x 8cm	1 pc.	2 x 120 pcs
AT-NFF-S 3	50cm x 75cm	ø 7cm	1 pc.	2 x 120 pcs
AT-NFF-S 4	75cm x 90cm	ø 7cm	1 pc.	2 x 120 pcs
AT-NFF-S 5	75cm x 90cm	6cm x 8cm	1 pc.	2 x 120 pcs
AT-NFF-S 6	90cm x 120cm	ø 10cm	1 pc.	2 x 120 pcs
AT-NFF-S 21	50cm x 60cm	ø 7cm	1 pc.	2 x 300 pcs




60 g/m²

STERILE SURGICAL DRAPES WITH ADHESIVE CENTRAL FENESTRATION - 2-LAYERED


ref.	dimensions	fenestration	packaging unit	 bulk packaging
AT-NFFA-S 1 E	45cm x 45cm	ø 5cm	100 pcs	4 x 100 pcs
AT-NFFA-S 2 E	45cm x 75cm	6cm x 8cm	100 pcs	4 x 100 pcs
AT-NFFA-S 3 E	50cm x 60cm	ø 6cm	100 pcs	4 x 100 pcs
AT-NFFA-S 4 E	75cm x 90cm	ø 7cm	50 pcs	4 x 50 pcs
AT-NFFA-S 5 E	75cm x 90cm	6cm x 8cm	50 pcs	4 x 50 pcs
AT-NFFA-S 6 E	90cm x 120cm	ø 8cm	50 pcs	4 x 50 pcs

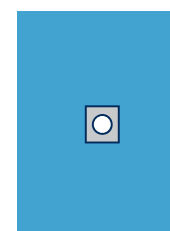



economic
version


40 g/m²

STERILE SURGICAL DRAPES WITH ADHESIVE CENTRAL FENESTRATION - 2-LAYERED

ref.	dimensions	fenestration	packaging unit	 bulk packaging
AT-NFFA-S 1	45cm x 45cm	ø 6cm	1 pc.	2 x 200 pcs
AT-NFFA-S 2	50cm x 75cm	6cm x 8cm	1 pc.	2 x 120 pcs
AT-NFFA-S 3	50cm x 75cm	ø 7cm	1 pc.	2 x 120 pcs
AT-NFFA-S 4	75cm x 90cm	ø 7cm	1 pc.	2 x 100 pcs
AT-NFFA-S 5	75cm x 90cm	6cm x 8cm	1 pc.	2 x 100 pcs
AT-NFFA-S 6	90cm x 120cm	ø 8cm	1 pc.	2 x 50 pcs
AT-NFFA-S 7	120cm x 150cm	ø 7cm	1 pc.	2 x 50 pcs
AT-NFFA-S 8	120cm x 150cm	ø 10cm	1 pc.	2 x 50 pcs
AT-NFFA-S 11	50cm x 60cm	6cm x 8cm	1 pc.	2 x 200 pcs




60 g/m²

Yankauer surgical suction cannula

standard CH21, sterile

features

- 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
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./double packaging: internal- foil, external- paper-foil

indication

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

REF	features	packaging	intermediate packaging
KO-00204	without suction control	1 pc.	50 pcs
KO-00214	with suction control	1 pc.	50 pcs



bulk packaging:
4 x 50 pcs



Yankauer surgical suction cannula

bulb tip CH23, sterile

features

- cannula with bulb tip with four lateral eyes, which prevent the tip from sticking to the tissues and one central opening
- 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
- universal stepped connector ensures tight connection with a wide range of suction connecting tubes
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./double packaging: internal- foil, external- paper-foil

indication

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

REF	features	packaging	intermediate packaging
KO-00104	without suction control	1 pc.	50 pcs
KO-00114	with suction control	1 pc.	50 pcs



bulk packaging:
4 x 50 pcs



dual-limb breathing circuit

sterile

features

- made of high quality EVA material, without PVC
- 15F/22M and 22F universal connector fits compatible products and devices for mechanical ventilation or anesthesia machine
- expandable arms with maximum length of 160 cm
- adjustable length of circuit enabling adjustment of length of respiratory system and optimization of dead space
- equipped with latex-free breathing bag: 3l (for adults) or 1l (for children)
- additional expandable tube, length: 100 cm
- elbow with luer lock port
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./foil

indication

- for patient's mechanical ventilation
- it enables transporting breathing mixture from equipment (ventilator, anesthesia machine) to respiratory protection device (e.g. tracheal tube, tracheostomy mask) and vice versa

REF	purpose	capacity of bag
OBWD-1601L	for children	1 liter
OBWD-1603L	for adults	3 liters



bulk packaging:
40 x 1 pc.



catheter mount with double swivel elbow connector

sterile

features

- smooth bore type made of medical PVC
- expandable type made of high quality PE, EVA
- universal patient connection: 22M/15F
- ventilation device side connector: 15M or 22F
- expandable version characterized by shape memorizing and by the ability to control the position of the connector
- double swivel elbow connector
- port for suctioning and bronchoscope secured with a stopper
- available in versions: smooth bore and expandable
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- used to connect the tracheostomy tube or endotracheal tube with the breathing circuit of the ventilation device
- provides greater mobility and rotation of the connection, increasing patient comfort and safety



REF	type	connection	length (without connectors)	intermediate packaging
PM-15-G	smooth bore (not expandable)	22M/15F-15M	15 cm	10 pcs
PM-22-G	smooth bore (not expandable)	22M/15F-22F	15 cm	10 pcs
PMR-15-K	expandable	22M/15F-15M	8-15 cm	10 pcs
PMR-22-K	expandable	22M/15F-22F	8-15 cm	10 pcs



bulk packaging:
10 x 10 pcs

foley catheter

3-way, silicone-coated latex, sterile

features

- made of soft and flexible latex, that is resistant to bending and kinking
- universal urine drainage port of the catheter fits into standard connectors in urine bags
- additional inlet for flushing out the bladder
- atraumatic, soft rounded, special tip facilitating insertion of the catheter to the bladder
- tip with two lateral eyes with smooth edges
- silicone-coated surface that allows atraumatic insertion of the catheter
- easy to fill and to empty, tear-resistant balloon
- plastic valve to ensure balloon tightness
- contains latex, does not contain phthalates
- single-use
- EO sterilized
- packaging: 1 pc./double packaging: internal- foil, external- paper-foil

indication

- to drain urine from the bladder

REF	length	balloon	size	colour	intermediate packaging
CFNL-3D-16-30-P	400 mm	30 ml	CH 16	orange	10 pcs
CFNL-3D-18-30-P	400 mm	30 ml	CH 18	red	10 pcs
CFNL-3D-20-30-P	400 mm	30 ml	CH 20	yellow	10 pcs
CFNL-3D-22-30-P	400 mm	30 ml	CH 22	purple	10 pcs
CFNL-3D-24-30-P	400 mm	30 ml	CH 24	dark blue	10 pcs
CFNL-3D-26-30-P	400 mm	30 ml	CH 26	pink	10 pcs



bulk packaging:
40 x 10 pcs

foley catheter

2-way, 100% silicone, sterile

features

- made of soft and flexible silicone, that reduces the allergic reaction of the mucous membranes and increases the patient's comfort
- atraumatic, soft rounded, special tip facilitating insertion of the catheter to the bladder
- tip with two lateral eyes with smooth edges
- universal urine drainage port of the catheter fits into standard connectors in urine bags
- radiopaque line along the entire length of the catheter
- easy to fill and to empty, tear-resistant balloon of various capacities
- plastic valve to ensure balloon tightness
- CH 6, CH 8, CH 10 size has a nylon guide to facilitate catheterization
- available in version with 10 ml sterile water pre-filled syringe with 10% glycerin to seal the balloon
- separately packed Catheter Spigot inside the packaging
- latex-free, phthalate-free
- single-use
- EO sterilized
- packaging: 1 pc./double packaging: internal- foil, external- paper-foil
- intermediate packaging: 10 pcs for REF: CFNS-2D-XX-XX-P, 5 pcs for REF: CFNSG-2D-XX-XX-P
- bulk packaging: 40 x 10 pcs for REF: CFNS-2D-XX-XX-P, 50 x 5 pcs for REF: CFNSG-2D-XX-XX-P

indication

- to drain urine from the bladder
- recommended for patients with blood clots or sediment in their urine



REF	intermediate packaging	REF with pre-filled syringe	intermediate packaging	length	balloon	size	colour
* CFNS-2D-06-03-P	10 pcs	CFNSG-2D-06-03-P	5 pcs	310 mm	3 ml	CH 6	pink
* CFNS-2D-08-05-P	10 pcs	CFNSG-2D-08-05-P	5 pcs	310 mm	3-5 ml	CH 8	black
* CFNS-2D-10-05-P	10 pcs	CFNSG-2D-10-05-P	5 pcs	310 mm	3-5 ml	CH 10	grey
* CFNS-2D-12-10-P	10 pcs	CFNSG-2D-12-10-P	5 pcs	400 mm	5-10 ml	CH 12	white
* CFNS-2D-14-10-P	10 pcs	CFNSG-2D-14-10-P	5 pcs	400 mm	5-10 ml	CH 14	green
* CFNS-2D-16-10-P	10 pcs	CFNSG-2D-16-10-P	5 pcs	400 mm	5-10 ml	CH 16	orange
* CFNS-2D-18-10-P	10 pcs	CFNSG-2D-18-10-P	5 pcs	400 mm	5-10 ml	CH 18	red
* CFNS-2D-20-10-P	10 pcs	CFNSG-2D-20-10-P	5 pcs	400 mm	5-10 ml	CH 20	yellow
* CFNS-2D-22-10-P	10 pcs	CFNSG-2D-22-10-P	5 pcs	400 mm	5-10 ml	CH 22	purple
* CFNS-2D-24-10-P	10 pcs	CFNSG-2D-24-10-P	5 pcs	400 mm	5-10 ml	CH 24	dark blue



bulk packaging:
50 x 5 pcs



bulk packaging:
*40 x 10 pcs

foley catheter

3-way, 100% silicone, sterile

features

- made of soft and flexible silicone, that reduces the allergic reaction of the mucous membranes and increases the patient's comfort
- universal urine drainage port of the catheter fits into standard connectors in urine bags
- additional inlet for flushing out the bladder
- atraumatic, soft rounded, special tip facilitating insertion of the catheter to the bladder
- tip with two lateral eyes with smooth edges
- radiopaque line along the entire length of the catheter
- easy to fill and to empty, tear-resistant balloon
- plastic valve to ensure balloon tightness
- separately packed Catheter Spigot inside the packaging
- latex-free, phthalate-free
- single-use
- EO sterilized
- packaging: 1 pc./double packaging: internal- foil, external- paper-foil

indication

- to drain urine from the bladder
- recommended for patients with blood clots or sediment in their urine

REF	length	balloon	size	colour	intermediate packaging
CFNS-3D-16-30-P	400 mm	30 ml	CH 16	orange	10 pcs
CFNS-3D-18-30-P	400 mm	30 ml	CH 18	red	10 pcs
CFNS-3D-20-30-P	400 mm	30 ml	CH 20	yellow	10 pcs
CFNS-3D-22-30-P	400 mm	30 ml	CH 22	purple	10 pcs
CFNS-3D-24-30-P	400 mm	30 ml	CH 24	dark blue	10 pcs



bulk packaging:
40 x 10 pcs

foley catheter

2-way with tiemann tip,
silicone-coated latex, sterile

features

- made of soft and flexible latex, that is resistant to bending and kinking
- universal urine drainage port of the catheter fits into standard connectors in urine bags
- angled tip makes it easier to overcome obstacles in the urinary tract
- tip with two lateral eyes with smooth edges
- silicone-coated surface that allows atraumatic insertion of the catheter
- easy to fill and to empty, tear-resistant balloon
- plastic valve to ensure balloon tightness
- contains latex, does not contain phthalates
- single-use
- EO sterilized
- packaging: 1 pc./double packaging: internal- foil, external- paper-foil

indication

- to drain urine from the bladder in the case of a narrowed urethra

REF	length	balloon	size	colour	intermediate packaging
CFTL-2D-12-10-P	400 mm	5-10 ml	CH 12	white	10 pcs
CFTL-2D-14-10-P	400 mm	5-10 ml	CH 14	green	10 pcs
CFTL-2D-16-10-P	400 mm	5-10 ml	CH 16	orange	10 pcs
CFTL-2D-18-10-P	400 mm	5-10 ml	CH 18	red	10 pcs
CFTL-2D-20-10-P	400 mm	5-10 ml	CH 20	yellow	10 pcs
CFTL-2D-22-10-P	400 mm	5-10 ml	CH 22	purple	10 pcs
CFTL-2D-24-10-P	400 mm	5-10 ml	CH 24	dark blue	10 pcs
CFTL-2D-12-30-P	400 mm	30 ml	CH 12	white	10 pcs
CFTL-2D-14-30-P	400 mm	30 ml	CH 14	green	10 pcs
CFTL-2D-16-30-P	400 mm	30 ml	CH 16	orange	10 pcs
CFTL-2D-18-30-P	400 mm	30 ml	CH 18	red	10 pcs
CFTL-2D-20-30-P	400 mm	30 ml	CH 20	yellow	10 pcs



bulk packaging:
40 x 10 pcs

endotracheal tube holder

sterile

features

- made of high-quality materials
- universal Velcro fasteners enabling fast and effective fixing of the holder around the head
- adjustable handle allows for easy and fast fixation of every size of endotracheal tube
- special design of the bite-piece prevents patient trauma or damaging the tube (by biting)
- additional opening allows for chyme, saliva and blood suction from the oral cavity
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- to stabilize the position of the endotracheal tube after its insertion into the trachea

REF	version	colour
SRI-N	horizontal fixation	blue-red
SRI-A	vertical fixation	green


bulk packaging:
100 x 1 pc.



tracheostomy tube

cuffed, sterile

features

- made of medical, flexible PVC
- swivel 15 mm connector
- flexible neckplates with slits for strap insertion to secure tube position
- soft, low-pressure, thin-walled cuff
- pilot balloon in contrasting colour clearly indicates the level of the cuff's inflation
- 2 fixation straps protected with foil
- clear size marking on the neckplates
- atraumatic, soft rounded tip, curved cannula
- radiopaque line
- equipped with obturator
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./rigid blister

indication

- to control respiratory tracts in people after tracheostomy
- introduced to the airways by a surgical incision of the tracheal's front wall to allow ventilation
- provides free breathing bypassing the nose, throat and larynx

REF	size	intermediate packaging
RTM-40	4.0	10 pcs
RTM-45	4.5	10 pcs
RTM-50	5.0	10 pcs
RTM-60	6.0	10 pcs
RTM-65	6.5	10 pcs
RTM-70	7.0	10 pcs
RTM-75	7.5	10 pcs
RTM-80	8.0	10 pcs
RTM-85	8.5	10 pcs
RTM-90	9.0	10 pcs
RTM-95	9.5	10 pcs
RTM-100	10.0	10 pcs


bulk packaging:
10 x 10 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

**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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