

cervical brush

standard, sterile

features

- straight shape enables obtaining samples from the cervical canal
- soft bristle tips to prevent irritation
- optimal outreach thanks to the long handle
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- device designed for obtaining cell samples from the cervix, cervical canal and transformation zone in smear tests

REF	type	intermediate packaging
SC-001	standard	100 pcs



bulk packaging:
10 x 100 pcs



cervical brush

special, sterile

features

- broom type enables obtaining samples from the cervix, cervical canal and transformation zone
- soft bristle tips enables precise collection of material for examination
- made entirely of polyethylene
- optimal outreach thanks to the long handle
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- device designed for obtaining cell samples from the cervix, cervical canal and transformation zone in smear tests

REF	type	intermediate packaging
SC-002	special	100 pcs



bulk packaging:
10 x 100 pcs



umbilical cord clamp

sterile

features

- made of polypropylene
- safe clamping teeth with rounded edges do not cut the umbilical cord
- serrated clamping surface of the arms stabilize the clamp on the umbilical cord, after closing it is not possible to open the clamp again
- double lock catch prevents accidental opening
- universal size
- single-use
- non-pyrogenic
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- device is designed for clamping the umbilical cord of a newborn in a labour ward in order to close the lumen of the umbilical blood vessels after cutting it off of the placenta

REF	size	colour	intermediate packaging
ZDPB	universal	white	50 pcs



bulk packaging:
50 x 50 pcs



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	length of tube	connector
ZO-212400104	CH21/CH24	210 cm	without suction control funnel-funnel
ZO-212400114	CH21/CH24	210 cm	without suction control funnel-funnel
ZO-402423104	CH21/CH24	400 cm	without suction control funnel-funnel
ZO-402423114	CH21/CH24	400 cm	without suction control funnel-funnel
ZO-2124001041	CH21/CH24	210 cm	without suction control funnel-funnel cut-to-fit
ZO-2124001141	CH21/CH24	210 cm	without suction control funnel-funnel cut-to-fit



bulk packaging:
50 x 1 set

DISPOSABLE MEDICAL BEDDING SET

non-sterile

features:

- made of polypropylene non-woven
- components:
 - bed sheet: 150 cm x 210 cm
 - quilt cover: 160 cm x 210 cm
 - pillow case: 70 cm x 80 cm



REF	grammage	colour	packaging unit
BT-ZES-25G3	25 g/m ²	green	1 set
BT-ZES-40G3	40 g/m ²	green	1 set
BT-ZES-40W3	40 g/m ²	white	1 set



bulk packaging:
25 x 1 set



available colours:



DISPOSABLE ABSORBENT UNDERPAD

non-sterile

features:

- composed of five layers:
 - lamine + cellulose wadding + cellulose pulp + cellulose wadding + PP nonwoven
- absorbent insert made of cellulose pulp
- impermeable foiled bottom
- single use



REF	dimensions	packaging unit
BT-PC4060	40 cm x 60 cm	25 pcs
BT-PC6060	60 cm x 60 cm	25 pcs
BT-PC6090	60 cm x 90 cm	25 pcs



bulk packaging:
4 x 25 pcs

DISPOSABLE ABSORBENT UNDERPAD

for operating table, non-sterile

features:

- quilted absorbent layer with addition of SAP (superabsorbent)
- composed of five layers: polypropylene non-woven, cellulose wadding, cellulose pulp with superabsorbent SAP, cellulose wadding, PE foil
- impermeable foiled bottom
- single use



REF	dimensions	packaging unit
BT-PC100225	100 cm x 225 cm	10 pcs



bulk packaging:
2 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

Notified Body



Rafal Byczkowski



Date: 2019-05-27

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

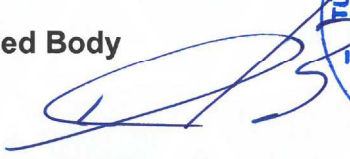
Products included:

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
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