

MANUFACTURER: ZARYS International Group sp. z o.o. sp.k.

ADDRESS: ul. Pod Borem 18, 41-808 Zabrze, Poland; T: +48 32 376 07 00-02,06 F: +48 32 370 38 08; www.zarys.com

CLASSIFICATION

class I medical device compliant with Medical Devices Regulation (EU) 2017/745 (MDR)

INTENDED PURPOSE

- device intended for holding dressings and for supporting and compressing body parts to treat sprains and strains, lymphoedema and to strengthen skin layers after surgery

FEATURES

- elastic supporting bandage, woven
- thanks to high cotton content it is safe for the skin and very well tolerated by people prone to allergies
- gentle, light
- stretchability min. 150%
- adapts well to body shapes
- can be sterilized by steam under positive pressure and by ethylene oxide
- equipped with a clip for fixing (band of 15 cm width equipped with 2 clips)
- reusable
- non-sterile
- shelf life: 5 years



CATALOGUE NUMBER	DIMENSIONS	UNIT PACKAGING (SALES)	TYPE OF PACKAGING	BULK PACKAGING CARTON
OE08400-E	8 cm x 4 m	1 pc.	box	124 x 1 pc.
OE08400P-E	8 cm x 4 m	1 pc.	paper	124 x 1 pc.
OE10400-E	10 cm x 4 m	1 pc.	box	108 x 1 pc.
OE10400P-E	10 cm x 4 m	1 pc.	paper	108 x 1 pc.
OE12400-E	12 cm x 4 m	1 pc.	box	96 x 1 pc.
OE12400P-E	12 cm x 4 m	1 pc.	paper	96 x 1 pc.
OE15400-E	15 cm x 4 m	1 pc.	box	72 x 1 pc.
OE15400P-E	15 cm x 4 m	1 pc.	paper	72 x 1 pc.
OE08500-E	8 cm x 5 m	1 pc.	box	124 x 1 pc.
OE08500P-E	8 cm x 5 m	1 pc.	paper	124 x 1 pc.
OE10500-E	10 cm x 5 m	1 pc.	box	108 x 1 pc.
OE10500P-E	10 cm x 5 m	1 pc.	paper	108 x 1 pc.
OE12500-E	12 cm x 5 m	1 pc.	box	96 x 1 pc.
OE12500P-E	12 cm x 5 m	1 pc.	paper	96 x 1 pc.
OE15500-E	15 cm x 5 m	1 pc.	box	72 x 1 pc.
OE15500P-E	15 cm x 5 m	1 pc.	paper	72 x 1 pc.

EU DECLARATION OF CONFORMITY



manufacturer: ZARYS International Group sp. z o.o. sp.k.
address: ul. Pod Borem 18, 41-808 Zabrze, Poland
contact: tel. +48 32 271 69 91, fax +48 32 274 72 84,
e-mail: zarys@zarys.pl, website: www.zarys.com
SRN: PL-MF-000000410

We declare under our sole responsibility that a medical device:

elastoBAND FLEX
elastic supporting bandage, woven, non-sterile

sizes*: **from 8cm x 4m to 15cm x 5m**

(*detailed list of products covered by this declaration is available in document TD-45-I.1.1.b-1.2- Identification – Annex 1, batch code - release document DZDO-01 – Annex 2)

classification:

- **class I, rule 1** (in accordance with Annex VIII of Regulation (EU) 2017/745)

Basic UDI-DI: **59079968M03040201HJ**

intended purpose: Device intended for holding dressings and for supporting and compressing body parts to treat sprains and strains, lymphoedema and to strengthen skin layers after surgery.

is in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

The device described above meets all applicable provisions of the Annex I of Regulation (EU) 2017/745. Conformity assessment procedure has been performed in accordance with Article 52 (7).

The medical device covered by the present declaration of conformity complies with European standards. The list of supervised standards is included in document TD-45-I.4.c-1 - Annex 3.

place and date of issue: Zabrze, 1.12.2021
name: Wioletta Gajda
position: Product Manager

PRODUCT MANAGER
ZARYS International Group sp. z o.o. sp.k.
Wioletta Gajda

.....
signature
(on behalf of the President of the General Partner's
Management Board)



GENERALNA NAZWA GRUPY/ GENERAL GROUP NAME: niejałowe opaski elastyczne/ non-sterile elastic bandages				
REF	nazwa handlowa/ trade name	nazwa wyrobu/ name of device		rozmiar/ size
elastoBAND FLEX				
OE08400	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	8cm x 4m
OE08400-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	8cm x 4m
OE08400P	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	8cm x 4m
OE08400P-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	8cm x 4m
OE08500	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	8cm x 5m
OE08500-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	8cm x 5m
OE08500P	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	8cm x 5m
OE08500P-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	8cm x 5m
OE10400	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	10cm x 4m
OE10400-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	10cm x 4m
OE10400P	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	10cm x 4m
OE10400P-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	10cm x 4m
OE10500	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	10cm x 5m
OE10500-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	10cm x 5m
OE10500P	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	10cm x 5m
OE10500P-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	10cm x 5m
OE12400	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	12cm x 4m
OE12400-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	12cm x 4m
OE12400P	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	12cm x 4m
OE12400P-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	12cm x 4m
OE12500	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	12cm x 5m
OE12500-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	12cm x 5m
OE12500P	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	12cm x 5m
OE12500P-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	12cm x 5m
OE15400	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	15cm x 4m
OE15400-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	15cm x 4m
OE15400P	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	15cm x 4m
OE15400P-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	15cm x 4m
OE15500	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	15cm x 5m
OE15500-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	15cm x 5m
OE15500P	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	15cm x 5m
OE15500P-E	elastoBAND FLEX	Opaska podtrzymująca elastyczna, tkana, niejałowa	<i>Elastic supporting bandage, woven, non-sterile</i>	15cm x 5m

PRODUCT MANAGER
 ZARYS International Group sp. z o.o. / s.p.a.
 Wioletta Gajda

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 0198 100 2241589

Certificate Holder: **ZARYS International Group**
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Scope: Manufacture of: sterile single-use medical devices, non-sterile single-use and multi-use medical devices; distribution of: medical devices, in vitro diagnostic devices

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-11-17 until 2025-11-16.

2022-11-17

Grzegorz Guabka

TÜV Rheinland Polska Sp. z o.o.
ul. Wolności 347, 41-800 Zabrze

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, production and distribution of sterile:
surgical kits, procedure sets, surgical drapes and sets of surgical
drapes.
Production 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 abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84951712-170
Effective date: 2021-05-14
Expiry date: 2023-06-08
Issue date: 2021-05-14



Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

The scope of certification includes the following manufacturing sites:

No.	Facility	Scope
/01	ZARYS International Group Spółka z o.o. sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Design, development and distribution of sterile: surgical kits, procedure sets, surgical drapes and sets of surgical drapes. Distribution of sterile and non-sterile disposable medical devices and non-sterile reusable medical devices. Distribution of in-vitro medical devices.
/02	ZARYS International Group Spółka z o.o. sp.k. ul. Guido Henckela Donnersmarcka 1 41-808 Zabrze Poland	Storage, release and distribution of medical devices.
/03	ZARYS International Group Spółka z o.o. Produkcja sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Production of sterile: surgical kits, procedure sets, surgical drapes and sets of surgical drapes.

Report No.: 84951712-170
Effective date: 2021-05-14
Expiry date: 2023-06-08
Issue date: 2021-05-14



Daniel Świątko
TÜV Rheinland LGA Products GmbH
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EC Certificate

Production Quality Assurance Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer: ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products:

- 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
- Sterile endotracheal tubes
- Sterile tracheostomy tubes

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.

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14



Daniel Świątko
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Production Quality Assurance Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer: ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Venturi masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizers
- 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
- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14



Daniel Swiatko
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EC Certificate

Production Quality Assurance Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer: ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves
- Sterile procedure kits

For the following medical devices the scope covers only the aspects of the manufacture concerned with securing and maintaining sterile conditions:

- Elastic bandages
- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Alginate dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes

Report No.: 84951712-170

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EC Certificate

Production Quality Assurance Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer: ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Fluid collection pouches
- Nelaton catheters
- Vaginal speculums
- Cervical brushes
- Urine bags
- Enema bags
- Tongue depressors
- Oropharyngeal airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Cannula stoppers
- Umbilical cord clamps

Replaces EC Certificate, Registration No.: DD 60139535 0001

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14



Daniel Świątko
TÜV Rheinland LGA Products GmbH
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Production Quality Assurance Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer: ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	ZARYS International Group Spółka z o.o. sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Activity: Final inspection and release.
/02	ZARYS International Group Spółka z o.o. sp.k. ul. Guido Henckela Donnersmarcka 1 41-808 Zabrze Poland	Activity: Final inspection and release.

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14



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TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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