



THREE-WAY STOPCOCK

sterile

TD-39

Attachment No. 3
point 2 pp. 2.3

Edition III
2018.01.26

Page 1/1

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

ADDRESS: ul. Pod Borem 18, 41-808 Zabrze, Poland, phone +48 32 376 07 00-02, fax. +48 32 370 38 08

INDICATION:

- Device designed for managing the flow of infusion fluids during administration
- Allows to switch the infusion flow path
- For blood pressure monitoring
- For direct drug / fluid supply

FEATURES:

- Made of polycarbonate
- Transparent design
- Clear optical identifier of open/close position (marked flow directions) operating in 360 degrees
- Consistent, straight flow channels and an optimal internal diameter ensure correct pressure measurement
- Rotating Luer Lock
- All inlets protected with stoppers
- Resistant to lipids
- Latex and DEHP-free
- Single-use
- Non-pyrogenic, non-toxic
- EO sterilized
- Shelf life: 5 years
- Individual packaging: paper-foil



REFERENCE

CATALOGUE NUMBER	COLOUR	INDIVIDUAL PACKAGING	INTERMEDIATE PACKAGING	BULK PACKAGING
KT-002	blue	paper-foil	50 pcs	20 x 50 pcs

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

ADDRESS: ul. Pod Borem 18, 41-808 Zabrze, Poland, phone +48 32 376 07 00-02, fax. +48 32 370 38 08

INDICATII:

- Dispozitiv proiectat pentru controlul debitului solutiilor in timpul administrarii
- Permite schimbarea fluxului de infuzie
- Pentru monitorizarea presiunii sangvine
- Pentru administrarea directa de fluide sau solutii medicamentoase

PROPRIETATI:

- Fabricat din policarbonat
- Design transparent
- Identificarea clara a pozitiei inchis/deschis (directii marcate), rotire la 360 grade
- Canale interne drepte si cu diametru optim pentru asigurarea corecta a presiunii
- Conector Luer-Lock rotativ
- Toate conexiunile sunt dotate cu capacele de protectie
- Rezistent la lipide
- Nu contine latex sau DEHP
- De unica folosinta
- Aprogenic si netoxic
- Sterilizat cu EO (etilenoxid)
- Durata sterilizare: 5 ani
- Ambalat individual: hartie-folie plastic.



REFERENCE

COD CATALOG

KT-002

CULOARE

albastru

AMBALAJ INDIVIDUAL

hartie-folie

AMBALARE INTERMEDIARA

50 bucati

AMBALARE CUTIE

20 x50 bucati

Subsemnata MUSUROIA MIRELA, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015





THREE-WAY STOPCOCK KRANIK TRÓJDROŻNY

DEHP-free • bez ftalanów / sterile

REF KT-002

blue / niebieski

DE Dreiwegehahn blau
FR Robinet trois voies bleu
RU Краник трехходовой синий
CZ Třícestný kohout modrý
SK Trojcestný kohút modrý
ES Llave de tres vías azul
IT Rubinetto a tre vie azzurro
PT Torneira de três vias azul
HU Háromágú csap kék
RO Robinet cu trei căi albastru
LT Trišakis čiaupas, mėlynas

LV Trīskanālu krāniņš, zils
EE Kolmikkraan, sinine
SE Trevägskran, blå
DK 3-vejs hane, blå
NO Treveis stoppekran, blå
FI 3-tiehana, sininen
HR Ventil s tri ulaza, plavi
NL Driewegkraan, blauw
GR Στρόφιγγα 3-way, μπλε
TR Üç yollu musluk, mavi
AR مخرج ثلاثة ذو ازرق محبس



5 907996 819249 >



2019-04-10



21190410E



2022-04-09



ZARYS International Group
sp. z o.o. sp.k.
ul. Pod Borem 18
41-808 Zabrze, Poland
www.zarys.com.pl

1 szt./pc.



THREE-WAY STOPCOCK KRANIK TRÓJDROŻNY

DEHP-free • bez ftalanów / sterile

REF KT-002

blue / niebieski

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1 szt./pc.





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

Date: 2019-05-27

Notified Body


Rafal Byczkowski



Traducere din limba engleza



Certificat CE
Directiva 93/42/CEE Anexa V
Asigurarea Calitatii in Productie
Dispozitive medicale

Nr. de inregistrare: DD 60139535 0001

Raport Nr.: 26300232 017

Prodicator:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polonia

Produse:

(pentru produse si facilitati de productie, consultati anexa)

Inlocuieste Certificatul CE cu nr. de inregistrare: DD 60117020 0001

Data expirarii: 2024-05-27

Organul de certificare, prin prezentul, declara ca produsele enumerate respecta cerintele din cadrul Anexei V a Directivei 93/42/CEE. Producatorul mentionat mai sus a implementat si utilizeaza un sistem de asigurare a calitatii supus verificarii periodice, conform Anexei V, sectiunea 4 a directivei mentionate mai sus. Pentru lansarea pe itata a dispozitivelor din clasele IIb si III care constituie obiectul acestui certificat este necesar un certificat CE de examinare a tipului constructiv, solicitat de Anexa III.

Data intrarii in vigoare: 09.06.2019

Data: 27.05.2019

Organul de certificare
(Stampila TUV Rheinland)
Rafal Byczowski
(Semnatura indescifrabila)

TUV Rheinland LGA Products GmbH - Tillystralle 2 - 90431 Nurnberg
TUV Rheinland LGA Products GmbH este Organul de certificare, conform Directivei 93/42/CEE referitoare la dispozitivele medicale, cu numarul de identificare 0197.
101020 n 04.08 ®TUV, TUEV si TUV sunt marci inregistrate. Utilizarea si aplicarea lor necesita aprobarea prealabila.





TUV Rheinland
LGA Products GmbH
Tillystralle 2 - 90431 Nurnberg

Anexa la certificat

Nr. de inregistrare: DD 60139535 0001

Raport Nr.: 26300232 017

Producator:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polonia

Produse incluse:

- Benzi de tifon sterile si nesterile
- Tampoane din tifon sterile si nesterile (cu sau fara fir metalic vizibil la radiografie)
- Bureti imbracati in tifon (cu fir metalic vizibil la radiografie/ cu cip pentru radiografie) sterili si nesterili
- Sfere din tifon sterile si nesterile (cu sau fara fir metalic vizibil la radiografie)
- Role de tifon sterile si nesterile (cu sau fara fir metalic vizibil la radiografie) –
- Tampoane netesute din tifon, sterile si nesterile (cu sau fara fir metalic vizibil la radiografie)
- Bandaje sterile din tifon impregnate cu parafina
- Robinete sterile cu trei derivatii
- Seturi sterile de transfuzie, de unica folosinta
- Seturi sterile de perfuzie, de unica folosinta
- Tuburi de extensie sterile pentru pompa de perfuzie

Data: 27.05.2019

Organul de certificare
(Stampila TUV Rheinland)
Rafal Byczowski
(Semnatura indescifrabila)

TUV Rheinland LGA Products GmbH - Tillystralle 2 - 90431 Nurnberg
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TUV Rheinland
LGA Products GmbH
Tillystralle 2 - 90431 Nurnberg

Anexa la certificat

Nr. de inregistrare: DD 60139535 0001

Raport Nr.: 26300232 017

Producator:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polonia

Produse incluse:

- Tuburi endotraheale sterile
- Tuburi sterile pentru traheostomie
- Circuite respiratorii sterile
- Catetere sterile
- Masti de anestezie nesterile
- Masti laringiene sterile
- Masti de oxigen sterile
- Masti sterile de ventilatie cu aplicatii multiple
- Masti sterile contra reinhalarii aerului expirat
- Masti sterile pentru atomizor
- Canule sterile nazale pentru oxigen
- Seturi sterile pentru atomizare
- Tuburi de oxigen sterile
- Catetere sterile pentru absorbtie
- Drenuri abdominale sterile
- Tuburi de alimentare sterile
- Tuburi sterile gastrice si duodenale
- Catetere sterile urologice
- Seturi sterile chirurgicale pentru absorbtie
- Canule sterile chirurgicale pentru absorbtie
- Seringi sterile de unica folosinta

Organul de certificare

Data: 27.05.2019

(Stampila TUV Rheinland)

Rafal Byczowski

(Semnatura indescifrabila)



TUV Rheinland LGA Products GmbH - Tillystralle 2 - 90431 Nurnberg
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TUV Rheinland
LGA Products GmbH
Tillystralle 2 - 90431 Nurnberg

Anexa la certificat

Nr. de inregistrare: DD 60139535 0001

Raport Nr.: 26300232 017

Producator:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polonia

Produse incluse:

- Seringi sterile pentru insulina
- Seringi sterile pentru tuberculina
- Ace hipodermice sterile
- Ace sterile pentru insulina
- Lantete sterile pentru prelevarea probelor de sange
- Canule intravenoase sterile
- Valve sterile fara ac
- Manusi chirurgicale sterile

Organul de certificare

Data: 27.05.2019

(Stampila TUV Rheinland)
Rafal Byczowski
(Semnatura indescifrabila)

TUV Rheinland LGA Products GmbH - Tillystralle 2 - 90431 Nurnberg
TUV Rheinland LGA Products GmbH este Organul de certificare, conform Directivei 93/42/CEE referitoare la dispozitivele medicale, cu numarul de identificare 0197.
101020 n 04.08 ®TUV, TUEV si TUV sunt marci inregistrate. Utilizarea si aplicarea lor necesita aprobarea prealabila.





TUV Rheinland
LGA Products GmbH
Tillystralle 2 - 90431 Nurnberg

Anexa la certificat

Nr. de inregistrare: DD 60139535 0001

Raport Nr.: 26300232 017

Producator:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polonia

Produse incluse:

Pentru urmatoarele dispozitive medicale, certificatul are ca obiect doar aspectele de asigurare si mentinere a conditiilor sterile de fabricatie:

- Bandaje adezive pentru fixarea canulelor
- Bandaje adezive pentru leziuni
- Bandaje oculare
- Folii de incizie
- Bandaje din folie transparenta
- Bureti absorbanti
- Bandaje absorbante pentru leziuni
- Manusi chirurgicale
- Campuri chirurgicale
- Seturi de campuri chirurgicale
- Pungi de colectare a fluidelor
- Catetere Nelaton

Organul de certificare

Data: 27.05.2019

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Rafal Byczowski
(Semnatura indescifrabila)

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TUV Rheinland
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Anexa la certificat

Nr. de inregistrare: DD 60139535 0001

Raport Nr.: 26300232 017

Producator:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polonia

Produse incluse:

Pentru urmatoarele dispozitive medicale, certificatul are ca obiect doar aspectele de asigurare si mentinere a conditiilor sterile de fabricatie:

- Specule vaginale
 - Perii cervicale
 - Pungi pentru urina
 - Apasatoare de limba
 - Circuite respiratorii Guedel
 - Stilete pentru intubatie
 - Suporturi pentru tuburi endotraheale
 - Tuburi de absorbtie
 - Canule retractabile
 - Bandaje cu alginat
 - Opritoare de canula
 - Cleme pentru cordonul ombilical
- Organul de certificare

Data: 27.05.2019

(Stampila TUV Rheinland)
Rafal Byczowski
(Semnatura indescifrabila)

TUV Rheinland LGA Products GmbH - Tillystralle 2 - 90431 Nurnberg
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TUV Rheinland
LGA Products GmbH
Tillystralle 2 - 90431 Nurnberg

Anexa la certificat

Nr. de inregistrare: DD 60139535 0001

Raport Nr.: 26300232 017

Prodicator:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polonia

Produse incluse:

ZARYS International Group
Spolka a ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Gustawa Eiffel 'a 15
44-109 Gliwice
Polonia
Activitate: Productie

Organul de certificare

Data: 27.05.2019

(Stampila TUV Rheinland)
Rafal Byczowski
(Semnatura indescifrabila)

TUV Rheinland LGA Products GmbH - Tillystralle 2 - 90431 Nurnberg
TUV Rheinland LGA Products GmbH este Organul de certificare, conform Directivei 93/42/CEE referitoare la dispozitivele medicale, cu numarul de identificare 0197.
101020 n 04.08 ®TUV, TUEV si TUV sunt marci inregistrate. Utilizarea si aplicarea lor necesita aprobarea prealabila.

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 0198 100 14345



Certificate Holder:



ZARYS International Group Sp. z o.o. Sp. k.
ul. Pod Borem 18
41-808 Zabrze
Poland

including the locations according to annex

Scope:

incoming inspection and distribution of disposable and reusable medical device and distribution of in-vitro medical 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 2018-05-04 until 2020-06-07.
First certification 2017

2018-05-04

Grzegorz Guabka

TÜV Rheinland Polska Sp. z o.o.
ul. Komitetu Obrony Robotników 56, 02-146 Warszawa

www.tuv.com



AC 129
QMS



 **TÜVRheinland®**
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 0198 100 14345



No.	Location	Scope
/01	ZARYS International Group Sp. z o.o. Sp. k. ul. Pod Borem 18 41-808 Zabrze Poland	Incoming inspection and distribution of disposable and reusable medical device and distribution of in-vitro medical devices
/02	ZARYS International Group Sp. z o.o. Sp. k. ul. Eiffel'a 15 44-105 Gliwice Poland	Incoming inspection and distribution of disposable and reusable medical device and distribution of in-vitro medical devices

2018-05-04

Grzegorz Guabka

TÜV Rheintand Polska Sp. z o.o.
ul. Komitetu Obrony Robotników 56, 02-146 Warszawa

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Certificat

Standard : **ISO 9001:2015**

Nr. de inreg. al certificatului 0198 100 14345



Titularul certificatului:

ZARYS International Group Sp. z o.o. Sp. k.
ul. Pod Borem 18 41-808 Zabrze
Polonia

Obiect: includerea locatiilor specificate in anexa

inspectia si distributia dispozitivelor medicale de unica folosinta si
reutilizabile si distributia de dispozitive medicale in-vitro

Procedura de audit a demonstrat respectarea cerintelor standardului ISO
9001:2015.

Valabilitate: Prezentul certificat este valabil de la 2018-05-04 pana la 2020-06-07.
Prima certificare: 2017

04.05.2018

Indescifrabil
TUV Rheinland Polska Sp. z o.o.
ul. Komitetu Obrony Robotnikow 56, 02-146 Warszawa

www.tuv.com



Page 1 of 1

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu
textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015



Anexa la certificat

Standard : **ISO 9001:2015**

Nr. de inreg. al certificatului 0198 100 14345

Nr.	Locatie	Obiect
/01	ZARYS International Group Sp. z o.o. Sp. k. ul. Pod Borem 18 41-808 Zabrze Polonia	Inspectia si distributia dispozitivelor medicale de unica folosinta si reutilizabile si distributia de dispozitive medicale in-vitro
/02	ZARYS International Group Spolka z ograniczona odpowiedzialnoscia spolka komandytowa ul. Gustawa Eiffel'a 15 44-109 Gliwice Polonia	Inspectia si distributia dispozitivelor medicale de unica folosinta si reutilizabile si distributia de dispozitive medicale in-vitro

04.05.2018

Indescifrabil

TUV Rheinland Polska Sp. z o.o.
ul. Komitetu Obrony Robotnikow 56, 02-146 Warszawa

www.tuv.com



Page 1 of 1



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

has established and applies a quality management system for medical devices
for the following scope:

**Production and distribution of disposable and reusable
medical devices and distribution of in-vitro medical devices
(see attachments for sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-11-07
Certificate Registration No.: SX 60120471 0001
An audit was performed. Report No.: 26300232 006
This Certificate is valid until: 2020-06-08

Certification Body



Date 2017-11-07


Maciej Sciera



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60120471 0001
Report No.: 26300232 006

Organization: ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Scope:

Sites included:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Poland

Activity:

Production, storage and distribution of medical devices

Certification Body



Date: 2017-11-07

Maciej Sciera





Certificat
Organul de certificare
TÜV Rheinland LGA Products GmbH
prin prezentul, certifica faptul ca organizatia:

ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zebrze
Polonia

a stabilit si aplica un sistem de management al calitatii dispozitivelor n
medicale, care are ca obiect:

Productia si distributia dispozitivelor medicale de unica folosinta si
reutilizabile si distributia dispozitivelor medicale in-vitro (vezi anexa pentru
unități incluse)

S-a dovedit indeplinirea cerintelor standardului
EN ISO 13485:2016

Sistemul de management al calitatii este supus inspectiilor anuale.

Data intrării în vigoare: 07.11.2017

Nr. Înregistrare: SX 60120471 0001

A fost efectuată o procedura de audit. Nr. Raport: 26300232 006

Prezentul certificat este valabil pana la data de: 08.06.2020

Sigla DAkks

Organ de certificare
Semnătură indescifrabilă
Ștampila rotundă TÜV Rheinland
Maciej Sciera

Data: 07.11.2017

TÜV Rheinland LGA Products GmbH – Tillystrasse 2 – 90431 Nürnberg

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu
textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015





TÜV Rheinland
LGA Products GmbH
Tillystrasse 2 – 90431 Nürnberg

Anexa la Certificat
Nr. Înregistrare: SX 60120471 0001
Nr. Raport: 26300232 006

Organizatia: ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zebrze
Polonia

Obiect: Locatii incluse:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Polonia

Activitate:
Productia, depozitarea si distributia dispozitivelor medicale

Sigla DAKKS

Data: 07.11.2017

Organ de certificare
Semnătură indescifrabilă
Ștampila rotundă TÜV Rheinland
Maciej Sciera

