

EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

Products:

- Analgetic control kits
- Angiographic accessories kits
- Aspiration catheters
- Balloon catheters
- Biliary prosthesis, catheters and kits
- Catheters and kits for dialysis
- Catheters for oxygen rhinoscopic administration
- Central venous pressure measuring kits
- Connectors
- Cystostomy catheters and kits
- Dilating catheters and dilators
- Drainage catheters and kits
- Drains
- Embolectomy and thrombectomy catheters
- Embolization catheters

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 84949468-50

Effective date: 2021-05-12

Expiry date: 2024-05-26

Issue date: 2021-05-12



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

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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
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- Extenders
- Feeding catheters
- Flat antibacterial filters
- Guide wires
- Gynecology catheters and kits
- Insemination catheters
- Introducers
- Kits for stent introduction
- Nephrostomy catheters and kits
- Pediatric catheters
- Puncture kits
- Rotating Y type adapters with and without valve
- Scalpels
- Stopcock manifolds and stopcocks
- Syringes
- Thermodilution kits
- Thrombolysis catheters and kits
- Treatment needles
- Ureteral catheters
- Urological catheters
- Vessel compression tourniquets
- Vessel irrigation catheters

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ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Vessel slings
- Sets for venous insufficiency treatment
- Infusion microcatheters
- Support catheters

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

- Aspirators
- Blockers
- Bottles, containers for aspiration
- Dilatation catheters for salivary duct
- Endoscopic balloon dilation catheters
- Guide wire grips
- Guide wire introduction tubes
- Insemination catheter universal luer lock caps
- Larynx anesthesia catheters
- Luer lock caps
- Mandrins
- Pushers
- Redon plugs

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Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Radial artery compression tourniquet kits
- Stents for salivary ducts
- Suction connectors
- Universal hubs luer lock

Replaces EC Certificate, Registration No.: HD 60144654 0001

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Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	BALTON Sp. z o.o. ul. Nowy Świat 7/14 00-496 Warszawa Poland	Activity: Administration.
/02	BALTON Sp. z o.o. ul. Modlińska 294 03-152 Warszawa Poland	Activity: Design and development, production and distribution of sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.
/03	BALTON Sp. z o.o. ul. Strzelnicza 3 18-300 Zambrów Poland	Activity: Production of disposable medical devices.
/04	BALTON Sp. z o.o. ul. Topolowa 23 05-119 Łajski Poland	Activity: Production of components and packaging materials for disposable medical devices and EO gas sterilization service according to EN ISO 11135:2014 standard.

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Daniel Swiatko
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Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Balton Sp. z o.o.

Headquarters: **ul. Nowy Świat 7/14, 00-496 Warszawa, Poland**

Manufacturing plants: **ul. Modlińska 294, 03-152 Warszawa, Poland**

ul. Topolowa 23, 05-119 Łajski, Poland

Scope:

Large Vessel Catheterization Catheters and Kits

Description of the device	Type	Intended use	Model	Risk class
Large vessel catheterization catheters and kits	single lumen with split cannula, pediatric	for intravenous therapy when peripheral venous access is impossible	KKDN, ZKDN, KKDND, ZKDND, KKDNT, ZKDNT, KKDNIV, ZKDNIV,	III
	single lumen, pediatric			
	single lumen			
	double lumen			
	triple lumen			
	quadruple lumen			

*In case of devices in Class III, this certificate independently does not authorize the manufacturer for the use of CE mark on the devices.

This certificate is valid only with annexes in case of successfully conducted annual surveillance audits.

ID number of the related audit report: **126-CE-190115**

Issue: 1

Issued: 25 March 2021

First issued: 25 March 2021

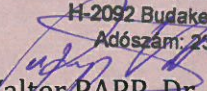
Start date of certified status: 27 March 2018

Expires:

25 May 2024

CE Certiso

Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13


Václav PAPP, Dr.
General Manager



The certificate covers the following products:

Large vessel catheterization catheter and kit single lumen, pediatric, with split cannula

KKDN1.2F^aIR; ZKDN1.2F^aIR; KKDN2F^aIR; ZKDN2F^aIR; KKDN1.2F^aIRH; ZKDN1.2F^aIRH;
KKDN2F^aIRH; ZKDN2F^aIRH.

Where

^a= length from 5 to 32 cm

IR = split cannula

H = hydrophilic coating

Large vessel catheterization catheter and kit single lumen, pediatric

KKDN2F^b; ZKDN2F^b; KKDN3F^c; ZKDN3F^c; KKDN4F^c; ZKDN4F^c; KKDN4.5F^c; ZKDN4.5F^c; KKDN2F^bH;
ZKDN2F^bH; KKDN3F^cH; ZKDN3F^cH; KKDN4F^cH; ZKDN4F^cH; KKDN4.5F^cH; ZKDN4.5F^cH

Where:

^b= length from 5 to 20 cm

^c= length from 5 to 45 cm

H = hydrophilic coating

Large vessel catheterization catheter and kit single lumen

KKDN5F^d; ZKDN5F^d; KKDN5.5F^d; ZKDN5.5F^d; KKDN6F^d; ZKDN6F^d; KKDN7F^d; ZKDN7F^d; KKDN7.5F^d;
ZKDN7.5F^d; KKDN8F^d; ZKDN8F^d; KKDN9F^d; ZKDN9F^d; KKDN10F^d; ZKDN10F^d; KKDN11F^d; ZKDN11F^d;
KKDN5F^dH; ZKDN5F^dH; KKDN5.5F^dH; ZKDN5.5F^dH; KKDN6F^dH; ZKDN6F^dH; KKDN7F^dH; ZKDN7F^dH;
KKDN7.5F^dH; ZKDN7.5F^dH; KKDN8F^dH; ZKDN8F^dH; KKDN9F^dH; ZKDN9F^dH; KKDN10F^dH;
ZKDN10F^dH; KKDN11F^dH; ZKDN11F^dH

Where:

^d= length from 5 to 60 cm

H = hydrophilic coating

Large vessel catheterization catheter and kit double lumen

KKDND3F^h; ZKDND3F^h; KKDND4F^h; ZKDND4F^h; KKDND4.5F^h; ZKDND4.5F^h; KKDND5F^h;
ZKDND5F^h; KKDND5.5F^h; ZKDND5.5F^h; KKDND6F^h; ZKDND6F^h; KKDND7F^h; ZKDND7F^h;
KKDND7.5F^h; ZKDND7.5F^h; KKDND8F^h; ZKDND8F^h; KKDND8.5F^h; ZKDND8.5F^h; KKDND9F^h;
ZKDND9F^h; KKDND10F^h; ZKDND10F^h; KKDND11F^h; ZKDND11F^h; KKDND3F^hH; ZKDND3F^hH;
KKDND4F^hH; ZKDND4F^hH; KKDND4.5F^hH; ZKDND4.5F^hH; KKDND5F^hH; ZKDND5F^hH;
KKDND5.5F^hH; ZKDND5.5F^hH; KKDND6F^hH; ZKDND6F^hH; KKDND7F^hH; ZKDND7F^hH;
KKDND7.5F^hH; ZKDND7.5F^hH; KKDND8F^hH; ZKDND8F^hH; KKDND8.5F^hH; ZKDND8.5F^hH;
KKDND9F^hH; ZKDND9F^hH; KKDND10F^hH; ZKDND10F^hH; KKDND11F^hH; ZKDND11F^hH

Where:

^h= length from 5 to 30 cm

H = hydrophilic coating

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Valter PAPP, Dr.
General Manager

CE Certiso
Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Large vessel catheterization catheter and kit triple lumen

KKDNT4Fh*; ZKDNT4Fh*; KKDNT4.5Fh*; ZKDNT4.5Fh*; KKDNT5Fh*; ZKDNT5Fh*; KKDNT5.5Fh*;
ZKDNT5.5Fh*; KKDNT6Fh*; ZKDNT6Fh*; KKDNT7Fh*; ZKDNT7Fh*; KKDNT7.5Fh*; ZKDNT7.5Fh*;
KKDNT8Fh*; ZKDNT8Fh*; KKDNT8.5Fh*; ZKDNT8.5Fh*; KKDNT9Fh*; ZKDNT9Fh*; KKDNT11Fh*;
ZKDNT11Fh*; KKDNT4Fh*H; ZKDNT4Fh*H; KKDNT4.5Fh*H; ZKDNT4.5Fh*H; KKDNT5Fh*H;
ZKDNT5Fh*H; KKDNT5.5Fh*H; ZKDNT5.5Fh*H; KKDNT6Fh*H; ZKDNT6Fh*H; KKDNT7Fh*H;
ZKDNT7Fh*H; KKDNT7.5Fh*H; ZKDNT7.5Fh*H; KKDNT8Fh*H; ZKDNT8Fh*H; KKDNT8.5Fh*H;
ZKDNT8.5Fh*H; KKDNT9Fh*H; ZKDNT9Fh*H; KKDNT11Fh*H; ZKDNT11Fh*H

Where:

h* = length from 5 to 30 cm

H = hydrophilic coating

Large vessel catheterization catheter and kit quadruple lumen

KKDNIV7Fg*; ZKDNIV7Fg*; KKDNIIV8Fg*; ZKDNIV8Fg*; KKDNIIV8.5Fg*; ZKDNIV8.5Fg*; KKDNIIV7Fg*H;
ZKDNIV7Fg*H; KKDNIIV8Fg*H; ZKDNIV8Fg*H; KKDNIIV8.5Fg*H; ZKDNIV8.5Fg*H

Where:

g* = length from 15cm to 30 cm

H = hydrophilic coating

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H-2092 Budakeszi, Erdő u. 101.
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Valter PAPP, Dr.
General Manager



There is possibility to add Nitinol guide wire to the kit

Codes according to the table:

ZKDN2F b * H *N ZKDN3F c * H *N ZKDN4F c * H *N ZKDN4.5F c * H *N ZKDN5F d * H *N ZKDN5.5F d * H *N ZKDN6F d * H *N ZKDN7F d * H *N ZKDN7.5F d * H *N ZKDN8F d * H *N ZKDN9F d * H *N ZKDN10F d * H *N ZKDN11F d * H *N Where: b *= length from 5 to 20 cm c *= length from 5 to 45 cm d *= length from 5 to 60 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *N ZKDND4F h * H *N ZKDND4.5F h * H *N ZKDND5F h * H *N ZKDND5.5F h * H *N ZKDND6F h * H *N ZKDND7F h * H *N ZKDND7.5F h * H *N ZKDND8F h * H *N ZKDND8.5F h * H *N ZKDND9F h * H *N ZKDND10F h * H *N ZKDND11F h * H *N Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *N ZKDNT4.5F h * H *N ZKDNT5F h * H *N ZKDNT5.5F h * H *N ZKDNT6F h * H *N ZKDNT7F h * H *N ZKDNT7.5F h * H *N ZKDNT8F h * H *N ZKDNT8.5F h * H *N ZKDNT9F h * H *N ZKDNT11F h * H *N Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *N ZKDNIV8F g * H *N ZKDNIV8.5F g * H *N Where: g *= length from 15 cm to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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Valter PAPP, Dr.
General Manager

There is possibility to add Y hub to the kit

Codes according to the table:

ZKDN2F b [*] H [*] Y ZKDN3F c [*] H [*] Y ZKDN4F d [*] H [*] Y ZKDN4.5F c [*] H [*] Y ZKDN5F d [*] H [*] Y ZKDN5.5F d [*] H [*] Y ZKDN6F d [*] H [*] Y ZKDN7F d [*] H [*] Y ZKDN7.5F d [*] H [*] Y ZKDN8F d [*] H [*] Y ZKDN9F d [*] H [*] Y ZKDN10F d [*] H [*] Y ZKDN11F d [*] H [*] Y Where: b [*] = length from 5 to 20 cm c [*] = length from 5 to 45 cm d [*] = length from 5 to 60 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h [*] H [*] Y ZKDND4F h [*] H [*] Y ZKDND4.5F h [*] H [*] Y ZKDND5F h [*] H [*] Y ZKDND5.5F h [*] H [*] Y ZKDND6F h [*] H [*] Y ZKDND7F h [*] H [*] Y ZKDND7.5F h [*] H [*] Y ZKDND8F h [*] H [*] YH [*] ZKDND8.5F h [*] H [*] Y ZKDND9F h [*] H [*] Y ZKDND10F h [*] H [*] Y ZKDND11F h [*] H [*] Y Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h [*] H [*] Y ZKDNT4.5F h [*] H [*] Y ZKDNT5F h [*] H [*] Y ZKDNT5.5F h [*] H [*] Y ZKDNT6F h [*] H [*] Y ZKDNT7F h [*] H [*] Y ZKDNT7.5F h [*] H [*] Y ZKDNT8F h [*] H [*] Y ZKDNT8.5F h [*] H [*] Y ZKDNT9F h [*] H [*] Y ZKDNT11F h [*] H [*] Y Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g [*] H [*] Y ZKDNIV8F g [*] H [*] Y ZKDNIV8.5F g [*] H [*] Y Where: g [*] = length from 15 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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Valter PAPP, Dr.
General Manager

There is possibility to add Guiding syringe 5 ml to the kit

Codes according to the table:

ZKDN2F b * H *SR ZKDN3F c * H *SR ZKDN4F c * H *SR ZKDN4.5F c * H *SR ZKDN5F d * H *SR ZKDN5.5F d * H *SR ZKDN6F d * H *SR ZKDN7F d * H *SR ZKDN7.5F d * H *SR ZKDN8F d * H *SR ZKDN9F d * H *SR ZKDN10F d * H *SR ZKDN11F d * H *SR Where: b *= length from 5 to 20 cm c *= length from 5 to 45 cm d *= length from 5 to 60 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *SR ZKDND4F h * H *SR ZKDND4.5F h * H *SR ZKDND5F h * H *SR ZKDND5.5F h * H *SR ZKDND6F h * H *SR ZKDND7F h * H *SR ZKDND7.5F h * H *SR ZKDND8F h * H *SR ZKDND8.5F h * H *SR ZKDND9F h * H *SR ZKDND10F h * H *SR ZKDND11F h * H *SR Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *SR ZKDNT4.5F h * H *SR ZKDNT5F h * H *SR ZKDNT5.5F h * H *SR ZKDNT6F h * H *SR ZKDNT7F h * H *SR ZKDNT7.5F h * H *SR ZKDNT8F h * H *SR ZKDNT8.5F h * H *SR ZKDNT9F h * H *SR ZKDNT11F h * H *SR Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *SR ZKDNIV8F g * H *SR ZKDNIV8.5F g * H *SR Where: g *= length from 15 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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Valter PAPP, Dr.
General Manager

There is possibility to add TEGO connector to the kit

Codes according to the table:

<p>ZKDN2Fb[*]H[*]KLLT ZKDN3Fc[*]H[*]KLLT ZKDN4Fc[*]H[*]KLLT ZKDN4.5Fc[*]H[*]KLLT ZKDN5Fd[*]H[*]KLLT ZKDN5.5Fd[*]H[*]KLLT ZKDN6Fd[*]H[*]KLLT ZKDN7Fd[*]H[*]KLLT ZKDN7.5Fd[*]H[*]KLLT ZKDN8Fd[*]H[*]KLLT ZKDN9Fd[*]H[*]KLLT ZKDN10Fd[*]H[*]KLLT ZKDN11Fd[*]H[*]KLLT</p> <p>Where: b[*]= length from 5 to 20 cm c[*]= length from 5 to 45 cm d[*]= length from 5 to 60 cm H[*]= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number</p>	<p>ZKDND3Fh[*]H[*]KLLT ZKDND4Fh[*]H[*]KLLT ZKDND4.5Fh[*]H[*]KLLT ZKDND5Fh[*]H[*]KLLT ZKDND5.5Fh[*]H[*]KLLT ZKDND6Fh[*]H[*]KLLT ZKDND7Fh[*]H[*]KLLT ZKDND7.5Fh[*]H[*]KLLT ZKDND8Fh[*]H[*]KLLT ZKDND8.5Fh[*]H[*]KLLT ZKDND9Fh[*]H[*]KLLT ZKDND10Fh[*]H[*]KLLT ZKDND11Fh[*]H[*]KLLT</p> <p>Where: h[*]= length from 5 to 30 cm H[*]= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number</p>	<p>ZKDNT4Fh[*]H[*]KLLT ZKDNT4.5Fh[*]H[*]KLLT ZKDNT5Fh[*]H[*]KLLT ZKDNT5.5Fh[*]H[*]KLLT ZKDNT6Fh[*]H[*]KLLT ZKDNT7Fh[*]H[*]KLLT ZKDNT7.5Fh[*]H[*]KLLT ZKDNT8Fh[*]H[*]KLLT ZKDNT8.5Fh[*]H[*]KLLT ZKDNT9Fh[*]H[*]KLLT ZKDNT11Fh[*]H[*]KLLT</p> <p>Where: h[*]= length from 5 to 30 cm H[*]= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number</p>	<p>ZKDNIV7Fg[*]H[*]KLLT ZKDNIV8Fg[*]H[*]KLLT ZKDNIV8.5Fg[*]H[*]KLLT</p> <p>Where: g[*]= length from 15 to 30 cm H[*]= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number</p>
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H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147048-2-13

Valter PAPP, Dr.
General Manager

There is possibility to add Blocking switch to the kit

Codes according to the table:

ZKDN2F b * H *BL ZKDN3F c * H *BL ZKDN4F c * H *BL ZKDN4.5F c * H *BL ZKDN5F d * H *BL ZKDN5.5F d * H *BL ZKDN6F d * H *BL ZKDN7F d * H *BL ZKDN7.5F d * H *BL ZKDN8F d * H *BL ZKDN9F d * H *BL ZKDN10F d * H *BL ZKDN11F d * H *BL Where: b *= length from 5 to 20 cm c *= length from 5 to 45 cm d *= length from 5 to 60 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *BL ZKDND4F h * H *BL ZKDND4.5F h * H *BL ZKDND5F h * H *BL ZKDND5.5F h * H *BL ZKDND6F h * H *BL ZKDND7F h * H *BL ZKDND7.5F h * H *BL ZKDND8F h * H *BL ZKDND8.5F h * H *BL ZKDND9F h * H *BL ZKDND10F h * H *BL ZKDND11F h * H *BL Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *BL ZKDNT4.5F h * H *BL ZKDNT5F h * H *BL ZKDNT5.5F h * H *BL ZKDNT6F h * H *BL ZKDNT7F h * H *BL ZKDNT7.5F h * H *BL ZKDNT8F h * H *BL ZKDNT8.5F h * H *BL ZKDNT9F h * H *BL ZKDNT11F h * H *BL Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *BL ZKDNIV8F g * H *BL ZKDNIV8.5F g * H *BL Where: g *= length from 15 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit then you should add H in the the catalog number
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CE Certiso
Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager

There is possibility to add One way valve cap to the kit

Codes according to the table:

ZKDN2F b * H * V ZKDN3F c * H * V ZKDN4F c * H * V ZKDN4.5F c * H * V ZKDN5F d * H * V ZKDN5.5F d * H * V ZKDN6F d * H * V ZKDN7F d * H * V ZKDN7.5F d * H * V ZKDN8F d * H * V ZKDN9F d * H * V ZKDN10F d * H * V ZKDN11F d * H * V Where: b *= length from 5 to 20 cm c *= length from 5 to 45 cm d *= length from 5 to 60 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H * V ZKDND4F h * H * V ZKDND4.5F h * H * V ZKDND5F h * H * V ZKDND5.5F h * H * V ZKDND6F h * H * V ZKDND7F h * H * V ZKDND7.5F h * H * V ZKDND8F h * H * V ZKDND8.5F h * H * V ZKDND9F h * H * V ZKDND10F h * H * V ZKDND11F h * H * V Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H * V ZKDNT4.5F h * H * V ZKDNT5F h * H * V ZKDNT5.5F h * H * V ZKDNT6F h * H * V ZKDNT7F h * H * V ZKDNT7.5F h * H * V ZKDNT8F h * H * V ZKDNT8.5F h * H * V ZKDNT9F h * H * V ZKDNT11F h * H * V Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H * V ZKDNIV8F g * H * V ZKDNIV8.5F g * H * V Where: g *= length from 15 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit then you should add H in the the catalog number
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Issue: 1
Issued: 25 March 2021

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H-2092 Budakeszi, Erdő u. 101.
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Valter PAPP, Dr.
General Manager

There is possibility to add ECG flex to the kit

Codes according to the table:

ZKDN2F b *H*E ZKDN3F c *H*E ZKDN4F c *H*E ZKDN4.5F c *H*E ZKDN5F d *H*E ZKDN5.5F d *H*E ZKDN6F d *H*E ZKDN7F d *H*E ZKDN7.5F d *H*E ZKDN8F d *H*E ZKDN9F d *H*E ZKDN10F d *H*E ZKDN11F d *H*E Where: b *= length from 5 to 20 cm c *= length from 5 to 45 cm d *=length from 5 to 60 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h *H*E ZKDND4F h *H*E ZKDND4.5F h *H*E ZKDND5F h *H*E ZKDND5.5F h *H*E ZKDND6F h *H*E ZKDND7F h *H*E ZKDND7.5F h *H*E ZKDND8F h *H*E ZKDND8.5F h *H*E ZKDND9F h *H*E ZKDND10F h *H*E ZKDND11F h *H*E Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h *H*E ZKDNT4.5F h *H*E ZKDNT5F h *H*E ZKDNT5.5F h *H*E ZKDNT6F h *H*E ZKDNT7F h *H*E ZKDNT7.5F h *H*E ZKDNT8F h *H*E ZKDNT8.5F h *H*E ZKDNT9F h *H*E ZKDNT11F h *H*E Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g *H*E ZKDNIV8F g *H*E ZKDNIV8.5F g *H*E Where: g *= length from 15 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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Valter PAPP, Dr.
General Manager

There is possibility to add Injection cap to the kit

Codes according to the table:

ZKDN2F b * H *KLLI ZKDN3F c * H *KLLI ZKDN4F c * H *KLLI ZKDN4.5F c * H *KLLI ZKDN5F d * H *KLLI ZKDN5.5F d * H *KLLI ZKDN6F d * H *KLLI ZKDN7F d * H *KLLI ZKDN7.5F d * H *KLLI ZKDN8F d * H *KLLI ZKDN9F d * H *KLLI ZKDN10F d * H *KLLI ZKDN11F d *KLLI Where: b *= length from 5 to 20 cm c *= length from 5 to 45 cm d *= length from 5 to 60 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *KLLI ZKDND4F h * H *KLLI ZKDND4.5F h * H *KLLI ZKDND5F h * H *KLLI ZKDND5.5F h * H *KLLI ZKDND6F h * H *KLLI ZKDND7F h * H *KLLI ZKDND7.5F h * H *KLLI ZKDND8F h * H *KLLI ZKDND8.5F h * H *KLLI ZKDND9F h * H *KLLI ZKDND10F h * H *KLLI ZKDND11F h * H *KLLI Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *KLLI ZKDNT4.5F h * H *KLLI ZKDNT5F h * H *KLLI ZKDNT5.5F h * H *KLLI ZKDNT6F h * H *KLLI ZKDNT7F h * H *KLLI ZKDNT7.5F h * H *KLLI ZKDNT8F h * H *KLLI ZKDNT8.5F h * H *KLLI ZKDNT9F h * H *KLLI ZKDNT11F h * H *KLLI Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *KLLI ZKDNIV8F g * H *KLLI ZKDNIV8.5F g * H *KLLI Where: g *= length from 15 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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General Manager

There is possibility to add Catheter introducer to the kit

Codes according to the table:

ZKDN2F b * H * IZK ZKDN3F c * H * IZK ZKDN4F c * H * IZK ZKDN4.5F c * H * IZK ZKDN5F d * H * IZK ZKDN5.5F d * H * IZK ZKDN6F d * H * IZK ZKDN7F d * H * IZK ZKDN7.5F d * H * IZK ZKDN8F d * H * IZK ZKDN9F d * H * IZK ZKDN10F d * H * IZK ZKDN11F d * H * IZK Where: b *= length from 5 to 20 cm c *= length from 5 to 45 cm d *= length from 5 to 60 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H * IZK ZKDND4F h * H * IZK ZKDND4.5F h * H * IZK ZKDND5F h * H * IZK ZKDND5.5F h * H * IZK ZKDND6F h * H * IZK ZKDND7F h * H * IZK ZKDND7.5F h * H * IZK ZKDND8F h * H * IZK ZKDND8.5F h * H * IZK ZKDND9F h * H * IZK ZKDND10F h * H * IZK ZKDND11F h * H * IZK Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H * IZK ZKDNT4.5F h * H * IZK ZKDNT5F h * H * IZK ZKDNT5.5F h * H * IZK ZKDNT6F h * H * IZK ZKDNT7F h * H * IZK ZKDNT7.5F h * H * IZK ZKDNT8F h * H * IZK ZKDNT8.5F h * H * IZK ZKDNT9F h * H * IZK ZKDNT11F h * H * IZK Where: h *= length from 5 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H * ZK ZKDNIV8F g * H * IZK ZKDNIV8.5F g * H * ZK Where: g *= length from 15 to 30 cm H *= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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General Manager

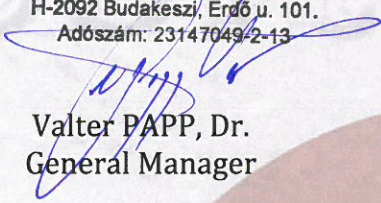
There is possibility to add V needle to the kit

Codes according to the table:

ZKDN5F d^* H* ¹ Y ZKDN5.5F d^* H* ¹ Y ZKDN6F d^* H* ¹ Y ZKDN7F d^* H* ¹ Y ZKDN7.5F d^* H* ¹ Y ZKDN8F d^* H* ¹ Y ZKDN9F d^* H* ¹ Y ZKDN10F d^* H* ¹ Y ZKDN11F d^* H* ¹ Y Where: d^* = length from 5 to 60 cm H* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h^* H* ¹ Y ZKDND4F h^* H* ¹ Y ZKDND4.5F h^* H* ¹ Y ZKDND5F h^* H* ¹ Y ZKDND5.5F h^* H* ¹ Y ZKDND6F h^* H* ¹ Y ZKDND7F h^* H* ¹ Y ZKDND7.5F h^* H* ¹ Y ZKDND8F h^* H* ¹ Y ZKDND8.5F h^* H* ¹ Y ZKDND9F h^* H* ¹ Y ZKDND10F h^* H* ¹ Y ZKDND11F h^* H* ¹ Y Where: h^* = length from 5 to 30 cm H* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h^* H* ¹ Y ZKDNT4.5F h^* H* ¹ Y ZKDNT5F h^* H* ¹ Y ZKDNT5.5F h^* H* ¹ Y ZKDNT6F h^* H* ¹ Y ZKDNT7F h^* H* ¹ Y ZKDNT7.5F h^* H* ¹ Y ZKDNT8F h^* H* ¹ Y ZKDNT8.5F h^* H* ¹ Y ZKDNT9F h^* H* ¹ Y ZKDNT11F h^* H* ¹ Y Where: h^* = length from 5 to 30 cm H* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g^* H* ¹ Y ZKDNIV8F g^* H* ¹ Y ZKDNIV8.5F g^* H* ¹ Y Where: g^* = length from 15 to 30 cm H* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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 Valter PAPP, Dr.
 General Manager



Additionally, it is possible to configure the kit by adding the selected or all the additional components:

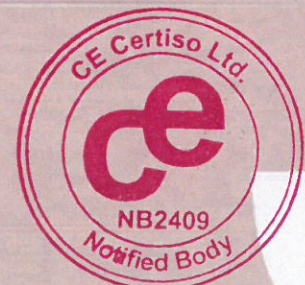
- **Y** - Y hub
- **SR** - Guiding syringe 5 ml
- **KLLT** - TEGO connector
- **BL** - Blocking switch
- **V** - One way valve cap
- **E** - ECG flex
- **KLLI** - Injection cap
- **IZK** - Catheter introducer
- **IY** - V needle
- **N** - Nitinol guide wire

Codes according to the table:

<p>ZKDN2F^{b*}H[*]i[*]</p> <p>ZKDN3F^{c*}H[*]i[*]</p> <p>ZKDN4F^{c*}H[*]i[*]</p> <p>ZKDN4.5F^{c*}H[*]i[*]</p> <p>ZKDN5F^{d*}H[*]i[*]</p> <p>ZKDN5.5F^{d*}H[*]i[*]</p> <p>ZKDN6F^{d*}H[*]i[*]</p> <p>ZKDN7F^{d*}H[*]i[*]</p> <p>ZKDN7.5F^{d*}H[*]i[*]</p> <p>ZKDN8F^{d*}H[*]i[*]</p> <p>ZKDN9F^{d*}H[*]i[*]</p> <p>ZKDN10F^{d*}H[*]i[*]</p> <p>ZKDN11F^{d*}H[*]i[*]</p> <p>Where:</p> <p>b*= length from 5 to 20 cm</p> <p>c*= length from 5 to 45 cm</p> <p>d*= length from 5 to 60 cm</p> <p>H*= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number</p> <p>i*= Y or/and SR or/and KLLT</p> <p>or/and BL or/and V or/and E or/and KLLI or/and IZK or/and N or/and IY</p> <p>(IY - it is possible adding only ZKDN5F)</p>	<p>ZKDND3F^{h*}H[*]i[*]</p> <p>ZKDND4F^{h*}H[*]i[*]</p> <p>ZKDND4.5F^{h*}H[*]i[*]</p> <p>ZKDND5F^{h*}H[*]i[*]</p> <p>ZKDND5.5F^{h*}H[*]i[*]</p> <p>ZKDND6F^{h*}H[*]i[*]</p> <p>ZKDND7F^{h*}H[*]i[*]</p> <p>ZKDND7.5F^{h*}H[*]i[*]</p> <p>ZKDND8F^{h*}H[*]i[*]</p> <p>ZKDND8.5F^{h*}H[*]i[*]</p> <p>ZKDND9F^{h*}H[*]i[*]</p> <p>ZKDND10F^{h*}H[*]i[*]</p> <p>ZKDND11F^{h*}H[*]i[*]</p> <p>Where:</p> <p>h*= length from 5 to 30 cm</p> <p>H*= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number</p> <p>i*= Y or/and SR or/and KLLT</p> <p>or/and BL or/and V or/and E or/and KLLI or/and IZK or/and IY or/and N</p>	<p>ZKDNT4F^{h*}H[*]i[*]</p> <p>ZKDNT4.5F^{h*}H[*]i[*]</p> <p>ZKDNT5F^{h*}H[*]i[*]</p> <p>ZKDNT5.5F^{h*}H[*]i[*]</p> <p>ZKDNT6F^{h*}H[*]i[*]</p> <p>ZKDNT7F^{h*}H[*]i[*]</p> <p>ZKDNT7.5F^{h*}H[*]i[*]</p> <p>ZKDNT8F^{h*}H[*]i[*]</p> <p>ZKDNT8.5F^{h*}H[*]i[*]</p> <p>ZKDNT9F^{h*}H[*]i[*]</p> <p>ZKDNT11F^{h*}H[*]i[*]</p> <p>Where:</p> <p>h*= length from 5 to 30 cm</p> <p>H*= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number</p> <p>i*= Y or/and SR or/and KLLT</p> <p>or/and BL or/and V or/and E or/and KLLI or/and IZK or/and IY or/and N</p>	<p>ZKDNIV7F^{g*}H[*]i[*]</p> <p>ZKDNIV8F^{g*}H[*]i[*]</p> <p>ZKDNIV8.5F^{g*}H[*]i[*]</p> <p>Where:</p> <p>g*= length from 15 to 30 cm</p> <p>H*= there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number</p> <p>i*= Y or/and SR or/and KLLT</p> <p>or/and BL or/and V or/and E or/and KLLI or/and IZK or/and IY or/and N</p>
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Issued: 25 March 2021

Valter PAPP, Dr.
General Manager



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1023580-1

Organization: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

Scope: Design and development, production and distribution of sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.
Provision of EO sterilization service according to EN ISO 11135:2014 standard.

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.: 84951149-20
Effective date: 2021-12-01
Expiry date: 2023-12-02
Issue date: 2021-12-01



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

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1023580-1

Organization: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	BALTON Sp. z o.o. ul. Nowy Świat 7/14 00-496 Warszawa Poland	Administration.
/02	BALTON Sp. z o.o. ul. Modlińska 294 03-152 Warszawa Poland	Design and development, production and distribution of sterile, disposable medical devices for dialysis, hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.
/03	BALTON Sp. z o.o. ul. Strzelnicza 3 18-300 Zambrów Poland	Production of disposable medical devices.
/04	BALTON Sp. z o.o. ul. Topolowa 23 05-119 Wieliszew-Łajski Poland	Production of metal elements for medical devices. Provision of EO sterilization service according to EN ISO 11135:2014 standard.

Report No.: 84951149-20
Effective date: 2021-12-01
Expiry date: 2023-12-02
Issue date: 2021-12-01