



RA/32/2022

Declaration of Conformity

Revision 1

BALTON Sp. z o. o.

ul. Nowy Świat 7/14

00-496 Warszawa

POLAND

SRN: PL-MF-000010568

declares under its sole responsibility that the products mentioned in the product list attached to this declaration are labelled with the CE safety mark. The granting of the mark is confirmed by certificate no. HD 1023580-1 valid from 12 May 2021 issued by the certification body TUV Rheinland.

This declaration of conformity covers sterile I sterile and class II a.

The declaration is based on the implemented Quality Management System compliant with the requirements of the harmonized standards:

- N ISO 13485:2016, which is confirmed by certificate no. HD 1023580-1 valid as of May 12, 2021 by the certification body TUV Rheinland LGA Products GmbH.

In addition, we declare that the distributed CE marked products, classified as Class I sterile and Class IIa, meet the requirements of the applicable European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and the amendment Directive 2007/47/EC.

This declaration of conformity is valid for all products bearing the CE mark and manufactured in the locations listed below:

Headquarter:	ul. Nowy Świat 7/14, 00-496 Warszawa, Poland
Manufacturing plant 1:	ul. Modlińska 294, 03-152 Warszawa, Poland
Manufacturing plant 2:	ul. Strzelnicza 3, 99-100 Zambrów, Poland
Manufacturing plant 3:	ul. Topolowa 23, 05-119 Łajski, Poland



Product groups covered by the Declaration of Conformity:

Class I sterile	Class IIa
1. Aspirators 2. Blockers 3. Bottles, containers for aspiration 4. Dilatation catheters for salivary duct 5. Endoscopic balloon dilation catheters 6. Guide wire grips 7. Guide wire introduction 8. Insemination catheter universal luer lock caps 9. Larynx anesthesia catheters 10. Luer lock caps 11. Mandrins 12. Pushers 13. Redon plugs 14. Radial artery compression tourniquet kits 15. Stents for salivary ducts 16. Suction connectors 17. Universal hubs luer-lock	1. Analgetic control kits 2. Angiographic accessories kits 3. Aspiration catheters 4. Balloon catheters 5. Biliary prosthesis, catheters and kits 6. Catheters and kits for dialysis 7. Catheters for oxygen rhinoscopic administration 8. Central venous pressure measuring kits 9. Connectors 10. Cystostomy catheters and kits 11. Dilating catheters and dilators 12. Drainage catheters and kits 13. Drains 14. Embolectomy and thrombectomy catheters 15. Embolization catheters 16. Extenders 17. Feeding catheters 18. Flat antibacterial filters 19. Guide wires 20. Gynecology catheters and kits 21. Insemination catheters 22. Introducers 23. Kit for stent introduction 24. Nephrostomy catheters and kits 25. Pediatric catheters 26. Puncture kits 27. Rotating Y type adapters with and without valve 28. Scalpels 29. Stopcock manifolds and stopcocks 30. Syringes 31. Thermodilution kits 32. Thrombolysis catheters and kits 33. Treatment needles 34. Ureteral catheters 35. Urological catheters 36. Vessel compression tourniquets 37. Vessel irrigation catheters 38. Vessel slings 39. Sets for venous insufficiency treatment 40. Infusion microcatheters 41. Support catheters

PRODUCT LIST, rev. 1

Sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.

Products included in the list below are covered by the Declaration of Conformity. All CE-marked products included in the list will be distributed by BALTON Sp. z o. o. in accordance with the provisions of the European Council Directive 93/42/EEC of 14.06.1993 concerning medical devices and the amendment to the Directive 2007/47/EC.

The list identifies products by name and model and Basic UDI-DI.

No.	Group	Name of medical device	Reference	EMDN code	Basic UDI-DI	Annex No
Class IIa						
1.	Analgetic control kit	Analgetic control kits	ZA	Z12019003	5901297ANALGETI CAP	Annex 1
2.	Angiographic accesories kit	Angio-pack kit	ZBAP		5901297ACCESO RIESJA	Annex 2
3.	Aspiration catheters	Surgical field aspiration catheter	DOPO	A060101	5901297ASPIRATI ONBY	Annex 3
		Surgical field aspiration catheter	KOPO	A060101		
		Surgical wounds aspiration catheter	KORO	A060101	5901297KORGJ	
		REDON type aspiration catheter	KOR	A06010199		
		Upper respiratory tracts aspiration catheter	KOGDO	R05010399	5901297KOGDOY	
4.	Balloon catheters	Extraction and occlusion catheters and kits	KDOIE	G03010199	5901297EOCCLUS IONCATHX7	Annex 4
		Extraction and occlusion catheter with triple channel	KTOIE			
5.	Biliary prosthesis, catheters and kits	STRAIGHT type prosthesis	E	P0502	5901297BILIARYP ROSTHX3	Annex 5
		GREENEN, type prosthesis	EGE			
		PIGTAIL type prosthesis	EPI			
		ZIMMON type prosthesis	EZI			
		Biliary ducts drainage kit	ZDBL	G03040301	5901297BILIARYV Q	
		Biliary prosthesis insertion with straight type prosthesis	ZPDZ	P0502	5901297BILIARYV Q	

		Oral biliary ducts drainage kit	ZPDDZ	G03040301	5901297BILIARYV Q	
		Biliary catheter	KDBL	G03040301	5901297BILIARYV Q	
		Catheter for bile ducts' plasty	CBPZ	G0301010402	5901297BILIARYV Q	
6.	Catheters and kits for dialysis	Catheters for dialysis	KDJY, KDJP, KDD, KDT,	F900201	5901297DIALYSIS 5W	Annex 6
		Kits for dialysis	ZDD, ZDJY, ZDJP, ZDT			
7.	Catheters for oxygen rhinoscopic administration	Catheters for oxygen rhinoscopic administration	KTPPN	R03010203	5901297OXYGEN CATHSU	Annex 7
8.	Central venous pressure measuring kit	Central venous pressure measuring kit	OCZ	Z1203020301	5901297OCZGJ	Annex 8
9.	Connectors	RYVA, RYVALUER Connector	RYVA, RYVALUER	A0701	5901297CONNECT ORS9B	Annex 9
		TEGO connector	KLLT			
10.	Cystostomy catheter and kit	Cystostomy catheters	KCYS	U0401	5901297CYSTOST OMY5	Annex 10
		Cystostomy kits	ZCYS			
11.	Dilating catheters and Dilators	Dilatators	DIL, ADILKR	C9002	5901297DILATOR S5Q	Annex 11
		Dilating catheter SOEHENDER type	KR			
12.	Drainage catheters and kits	Thorax drainage catheters with and without trocar	DKP, KDKPT	A0601010401	5901297DRAINAG E3D	
		One-step method drainage catheter and kit	KOSD, OSD	A060299	5901297DRAINAG EPERCUTAN7M	
		Two-step method drainage kit	ZPDA	A060299		
		Pericardial drainage kit	ZDWO	A060205	5901297DRAINAG E3D	Annex 12
		Percutaneous method abscess drainage double channel catheter	ZDRD		5901297DRAINAG E3D	
		Double channel method drainage abscess catheter	KDRD			
13.	Drains	Gastric tube	SZ	G020299	5901297GASTRIC 2G	Annex 13
		Gastric catheter	KZ	G020299	5901297GASTRIC 2G	
		Duodenal tube	SD	G020299	5901297DUODEN ALTUBEU6	

		Rectal tube	SR	G020299	5901297GASTRIC 2G	
		Ventral drain	DB	A060102	5901297VENTRAL DRAINSHW	
		Drains	D, DT, DH	A060102	5901297DRAINSW G	
14.	Embolectomy and trombectomy catheters	Embolectomy and trombectomy catheters	EFB, EFBD, EFBDP	C019002	5901297EMBOLEC TOMYRE	Annex 14
15.	Embolization catheters	Varicocele embolization catheter	KEZPN		590129KEZPN2W	Annex 15
16.	Extenders	Infusion pump extenders with luer hub	PPI_L	A03020101	5901297PPIGROU PH3	Annex 16
		Infusion pump extenders with luer-lock hub	PPI_LL			
		Infusion pump extenders with three- way stopcock and luer-lock hub	PPIK3			
		Bronchoscope extender	PDB		5901297EXTENDE RSUF	
		Surgical field aspiration extender	POPO	A060101	5901297ASPIRATI ONBY	
		Universal extender of low-pressure	PUN	A03020101	5901297EXTENDE RSUF	
		Extenders of high- pressure	PW	A03020102	5901297HIGHEXT ENDERQJ	
		Extenders of high- pressure valve duo	PYWZ			
		Dialysis extender for dializator rinsing	PD		5901297EXTENDE RSUF	
		Dialysis extender "Y"	PUDY	F9080	5901297EXTENDE RSUF	
		Connecting tube for one-step method drainage	POSD	A060299	5901297EXTENDE RSUF	
17.	Feeding catheters	Feeding catheters	KK	G020201	5901297FEEDING CATHBV	Annex 17
18.	Flat antibacterial filters	Flat antibacterial filters	FPBP	N02010199	5901297FILTERS2 L	Annex 18
19.	Guide wires	Steel guide wire coating PTFE	PL_T, PLJ_T, P_T, PJ_T, P_SRMT, PJ_SRMT,	C04030202	5901297GUIDEWI RESCP	Annex 19

			P_AEST, PJ_AEST, P_AUST, PJ_AUST, P_ASST, P_CT, P_CST, P_CMT, P_CLT			
		Polymer guide wire with hydrophilic coating ENTER	PPN, PPNA	C04030202	5901297PPNH6	
		Steel guide wire	P, PJ	C04030202	5901297GUIDEWI RESCP	
		Steel guide wire with hydrophilic coating	P_H, PJ_H			
		Steel guide wire super stiff	P_L, PJ_L			
20.	Gynecology catheters and kits	Extracervical insemination pessary	KPINN	U08020199	5901297GYNECOL OGYG9	Annex 20
		Intracervical insemination pessary	KPINW			
		Hysterosalpingography catheters	KHSG	U080102	5901297GYNECOL OGYG9	
		Hysterosalpingography kits	ZHSG			
		Endometric biopsy kits	ZBE	A010201	5901297ZBEGU	
		Egg cell uptake kits	ZPKJ	U08020201	5901297GYNECOL OGYG9	
		Artificial amniotic fluid transfusion kits	ZPSPO	U1099	5901297ZPSPO9F	
		Embryo transfer kits	ZTZ	U08020102	5901297GYNECOL OGYG9	
21.	Insemination catheters	Insemination catheter; Straight	KIP	U08020101	5901297CATHETE RSINSEMINQQ	Annex 21
		Insemination catheter; F type	KF			
		Insemination catheter	KI			
22.	Introducers	Kit to introduce and exchange catheters and endocavitary electrodes, with or without hemostasis valve	INT INT_H INT_T INT_M INT_A INT_KR	C05	5901297INTRODU CERSF7	Annex 22

			INT_MH INT_KR_M INT_KR_H INT_KR_T INT_KR_TP INT_KR_MP			
		Kit to introduce and exchange catheters and endocavitary electrodes with hemostasis valve – Triple Access Hemostasis Introducer	TKATINT	C05		
		Kit to introduce electrodes with split sheath	ZWERK	C0503	5901297ZWERK8Q	
23.	Kits for stent introduction	Kits for stent introduction	ZSWM	U020302	5901297STINTOD UCTIONYB	Annex 23
24.	Nephrostomy catheters and kits	Nephrostomy catheters	KNEF, KNPIG, KNPIGTR	U040201	5901297NEPHROS TOMYDM	Annex 24
		Nephrostomy kits	ZNEF			
		Kit for percutaneous nephrostomy	SNEF			
		Kit for catheters exchange	ZWK	U040299	5901297NEPHROS TOMYDM	
25.	Pediatric catheters	Pediatric catheters for the umbilical cord vein	KP	Z12030399	5901297PEDIATRI CCATHLN	Annex 25
26.	Puncture kits	Puncture kit	ZDP		5901297NEPHROS TOMYDM	Annex 26
27.	Rotating Y type adapter with and without valve	Rotating Y type adapter with valve	YCONV	A070199	5901297ADAPTER SYB	Annex 27
		Rotating Y type adapter without valve	YCON	A070199	5901297ADAPTER SYB	
28.	Scalpels	Scalpel	S	K01020201	5901297SCALPEL S7R	Annex 28
29.	Stopcock manifolds and Stopcocks	Three - way stopcock	K3V	A0703	5901297STOPC OCKS3P	Annex 29
		Three - way stopcock high-pressure	K3V20BARS			
		Three - way stopcock black high-pressure	K3V20BARSC Z			

		Three - way stopcock black	K3VCZ			
		Three - way stopcock red	K3VCZE			
		Three - way stopcock plug	K3VK			
		Three - way stopcock blue	K3VN			
		One - way stopcock high-pressure	K1V20BARS			
		Two stopcock manifolds	RAM2			
		Three stopcock manifolds	RAM3			
		Five stopcock manifolds	RAM5			
30.	Syringes	Syringe Luer-Lock	S_LL	C010401020180	5901297SYRINGE SQJ	Annex 30
		High-pressure syringes	SW		5901297INFLATION DEVICE BM	
31.	Thermodilution kits	BALKAT thermodilution kits	ZKT	C019003	5901297THERMO DILUTION M3	Annex 31
32.	Thrombolysis catheters and kits	Thrombolysis catheters	PT	Z12059003	5901297THROMBOLYSISK6	Annex 32
		Thrombolysis kits	ZPT	Z12059003		
33.	Treatment needles	Two pieces needle for drainage	IOSD	A060299	5901297NEEDLES X4	Annex 33
		Biopsy needles type Madayag and Westcott	IBM, IBW	A01020102	5901297NEEDLES X4	
		Angiographic needle one-piece	IP	A019010	5901297NEEDLES X4	
		Angiographic needle two-piece	IAD	A019010	5901297NEEDLES X4	
		Hemodialysis needles	IZD, ITD, IDY	A010401	5901297NEEDLES X4	
		Guiding needle	IPT	A0180	5901297NEEDLES X4	
		Egg cell uptake needles	IPKJ	U08020201	5901297GYNECOLOGY G9	
		Nephrostomy needles	IN, ID	U040299	5901297NEEDLES X4	

34.	Ureteral catheters	Ureteral catheter Couvelaire type	KMC	U0201	5901297URETERA LKF	Annex 34
		Ureteral catheter Nelaton type	KMN			
		Ureteral catheter Tiemann type	KMT			
		Ureteral catheters X-Ray single Pigtail type	KMS			
		Ureteral catheters X-Ray double Pigtail type	KMP			
		Ureteral catheters Olive type	KMO			
		Ureteral catheters Zeiss type	KMZ			
		Urethral calibration catheter	KKCM	U010101	5901297URETERA LKF	
35.	Urological catheters	Urological tract stone retrieval basket	KDKU	U010102	5901297UROLOG YEE	Annex 35
		Urological catheter COUVELAIRE type	KUC			
		Urological catheter NELATON type	KUN	U010105		
		Urological catheter TIEMANN type	KUT	U010102		
36.	Vessels compression tourniquets	Vessels compression tourniquet	T	C90010301	5901297TOURNIQ UETSXQ	Annex 36
37.	Vessel irrigation catheters	Vessel irrigation catheters	PNK	A06010103	5901297IRRIGATI ONF8	Annex 37
38.	Vessel slings	Vessel slings	P		5901297SLINGS4 G	Annex 38
		Liver slings	PDW			
39.	Set for venous insufficiency treatment	Set for venous insufficiency treatment FLEBOGRIF	FLE	C01901999	5901297PHLEBOL OGYAL	Annex 39
40.	Infusion microcatheter	Infusion microcatheter DELIVER	MCI	C0104020205	5901297MICROCA THETERSYM	Annex 40
41.	Support catheter	Support catheters Soter	SP	C0105	5901297SUPPORT GH	Annex 41

No	Grupa	Name of medical device	Reference	Kod EMDN	Basic UDI-DI	Annex No
Class I sterile						
1.	Aspirators	Neonatal meconium aspirator	ASP	V028099	5901297ASPIRATORSDH	Annex 42
2.	Blockers	Blocking switch	BL	A03010103	5901297BLOCKERS4H	Annex 43
3.	Bottles, containers for aspiration	Bottle for long-lasting wound aspiration	BS	A060101	5901297BOTTLES5J	Annex 44
4.	Dilatation catheters for salivary duct	Dilatators for salivary duct with high-pressure balloon	HPB4	G010303	5901297SALIVARYBR	Annex 45
		Dilatators for salivary duct with low-pressure balloon	LPB			
5.	Endoscopic balloon dilation catheters	TROYCA Endoscopic balloon dilation catheters for esophageal, pyloric and colonic, FW - fixed wire type TROYCA	EBRS	G03010199	5901297ENDOSCOPIC7W	Annex 46
		Endoscopic balloon dilation catheters for esophageal, pyloric and colonic, WG – guide wire type	EBRP			
6.	Guide wire grips	TORQUER	TORQUER	C0480	5901297INTROTUBESSL	Annex 47



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7.	Guide wire introduction tube	Guide wire introduction tube	RWP		5901297INTRO TUBESSL	Annex 48
8.	Insemination catheter universal luer lock caps	Insemination catheter universal Luer-Lock cap	NZLLKI		5901297INSEMI NATIONCAPPL	Annex 49
9.	Larynx anaesthesia catheters	Larynx anaesthesia catheter	KZK	A 99	5901297LARYN X2H	Annex 50
10.	Luer lock caps	Luer – Lock caps	KLL, KLB, KLLB, KLLN	A070599	5901297HUBSC APSPLUGS6	Annex 51
11.	Mandrins	Mandrin	M		5901297MAND RINS6W	Annex 52
12.	Pushers	Pusher	P		5901297PUSHE RSCK	Annex 53
13.	Redon plugs	Redon Plug	ZRD, ZRM		5901297REDO NPLUGRB	Annex 54
14.	Radial artery compression tourniquet kits	Radial artery compression tourniquet kit	ZOUDP	C90010301	5901297ZOUDP 8G	Annex 55
15.	Stents for salivary ducts	Stents for salivary ducts	DP		5901297DPTK	Annex 56
16.	Suction connectors	Suction connectors	LDS	A0701	5901297SUNCT IONCONN5	Annex 57
		Foleys's connector	LCF			
		Urologic connector	LU			
		Connector with plug	LZ			
17.	Universal hubs luer-lock	Uniwersal hub Luer-Lock	ANEMBF, ANEMBMF		5901297HUBLL Z2	Annex 58

27 June 2022
Warsaw, Polska

A. Prajmał-Ołanowska

Regulatory Affairs Director

M. Ziżyńska

Person responsible for regulatory compliance

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The annexes are only valid with CE Declaration of Conformity No. RA/32/2022

This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.

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Annex 14

Embolectomy and thrombectomy catheters

No	Name of medical device	Reference
1	Embolectomy and thrombectomy catheters (EFBVVXX) VV – sizes: 2, 3, 4, 5, 6, 7, 8, 10F XX – length: 40, 60, 80 cm Embolectomy and thrombectomy catheters (EFBDVVXX) D - double channel catheter VV – sizes: 3, 4, 5, 6, 7, 8F XX – length: 40, 80 cm Embolectomy and thrombectomy catheters (EFBDPVVXX) P – under the guide wire VV – sizes: 3, 4, 5, 6, 7, 8F XX – length: 40, 80 cm	EFB2F40, EFB2F60, EFB2F80, EFB3F40, EFB3F60, EFB3F80, EFB4F40, EFB4F60, EFB4F80, EFB5F40, EFB5F60, EFB5F80, EFB6F40, EFB6F80, EFB7F40, EFB7F80, EFB8F40, EFB8F80, EFB10F40, EFB10F80 EFBD3F40, EFBD3F80, EFBD4F40, EFBD4F80, EFBD5F40, EFBD5F80, EFBD6F40, EFBD6F80, EFBD7F40, EFBD7F80, EFBD8F40, EFBD8F80 EFBDP3F40, EFBDP3F80, EFBDP4F40, EFBDP4F80, EFBDP5F40, EFBDP5F80, EFBDP6F40, EFBDP6F80, EFBDP7F40, EFBDP7F80, EFBDP8F40, EFBDP8F80

