

Declaration of Conformity

Revision 4

Balton sp. z o.o.

ul. Nowy Świat 7/14

00-496 Warszawa

POLAND

SRN: PL-MF-000010568

declares under his 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 certificates:

Device	EC Certificate
Peripheral angioplasty catheter LOVIX	145090-21-03-25

issued by the CE Certiso Ltd. certification body in Budakeszi, Hungary, bearing the identification mark of the notified body - 2409. These products conform the required technical documentation in accordance with the requirements of Annex II of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and the amendment to Directive 2007/47/EC.

In addition, we declare that the distributed CE marked products, classified as Class IIb Rule 6, comply with the requirements of the applicable European Council Directive.

This declaration is supported by the Quality System developed base on the harmonized standards:

- EN ISO 13485:2016, Certificate no. SX 1023580-1 Notified Body TÜV Rheinland LGA Products GmbH.

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

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

PRODUCT LIST

Products included in the list below are covered by the Declaration of Conformity no RA 25/2023-EN. 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.

Product type according CE certificate and intended purpose	Type	Model	References	EMDN	Basic UDI-DI
Peripheral angioplasty catheter / Indicated for improving peripheral luminal diameter in the following patients with symptomatic peripheral vessels disease caused by de novo atherosclerotic changes or restenosis in peripheral arteries, with reference diameter of the vessel from 1.25 to 16.0 mm	LOVIX	PBA_AxBCD, PBARX_AxB140 <i>Where:</i> PBA - peripheral Angioplasty Catheter, Over The Wire type PBARX - peripheral Angioplasty Catheter, Rapid Exchange type A - nominal balloon diameter (mm) B - nominal balloon length (mm) C - guide wire size D - catheter length (cm)	According to the Annex I	C0104020201 / PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) DILATATION CATHETERS	5901297PBCF6

22 June 2023
Warsaw, Poland

President of the Board

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ANNEX I - LOVIX

Peripheral angioplasty catheter LOVIX, RAPID EXCHANGE type

Catalogue number	Nominal balloon diameter [mm]	Nominal balloon length [mm]
PBARXBxC140	<i>B</i>	<i>C</i>
	1.25, 1.5, 1.75	10, 15, 20, 25, 30, 35, 40
	2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0	10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 150, 180, 200, 250

Reference:

PBARX1.25x10140, PBARX1.25x15140, PBARX1.25x20140, PBARX1.25x25140, PBARX1.25x30140, PBARX1.25x35140, PBARX1.25x40140

PBARX1.5x10140, PBARX1.5x15140, PBARX1.5x20140, PBARX1.5x25140, PBARX1.5x30140, PBARX1.5x35140, PBARX1.5x40140

PBARX1.75x10140, PBARX1.75x15140, PBARX1.75x20140, PBARX1.75x25140, PBARX1.75x30140, PBARX1.75x35140, PBARX1.75x40140

PBARX2.0x10140, PBARX2.0x15140, PBARX2.0x20140, PBARX2.0x25140, PBARX2.0x30140, PBARX2.0x35140, PBARX2.0x40140, PBARX2.0x45140, PBARX2.0x50140, PBARX2.0x55140, PBARX2.0x60140, PBARX2.0x65140, PBARX2.0x70140, PBARX2.0x75140, PBARX2.0x80140, PBARX2.0x85140, PBARX2.0x90140, PBARX2.0x95140, PBARX2.0x100140, PBARX2.0x150140, PBARX2.0x180140, PBARX2.0x200140, PBARX2.0x250140

PBARX2.25x10140, PBARX2.25x15140, PBARX2.25x20140, PBARX2.25x25140, PBARX2.25x30140, PBARX2.25x35140, PBARX2.25x40140, PBARX2.25x45140, PBARX2.25x50140, PBARX2.25x55140, PBARX2.25x60140, PBARX2.25x65140, PBARX2.25x70140, PBARX2.25x75140, PBARX2.25x80140, PBARX2.25x85140, PBARX2.25x90140, PBARX2.25x95140, PBARX2.25x100140, PBARX2.25x150140, PBARX2.25x180140, PBARX2.25x200140, PBARX2.25x250140

PBARX2.5x10140, PBARX2.5x15140, PBARX2.5x20140, PBARX2.5x25140, PBARX2.5x30140, PBARX2.5x35140, PBARX2.5x40140, PBARX2.5x45140, PBARX2.5x50140, PBARX2.5x55140, PBARX2.5x60140, PBARX2.5x65140, PBARX2.5x70140, PBARX2.5x75140, PBARX2.5x80140, PBARX2.5x85140, PBARX2.5x90140, PBARX2.5x95140, PBARX2.5x100140, PBARX2.5x150140, PBARX2.5x180140, PBARX2.5x200140, PBARX2.5x250140

PBARX2.75x10140, PBARX2.75x15140, PBARX2.75x20140, PBARX2.75x25140, PBARX2.75x30140, PBARX2.75x35140, PBARX2.75x40140, PBARX2.75x45140, PBARX2.75x50140, PBARX2.75x55140, PBARX2.75x60140, PBARX2.75x65140, PBARX2.75x70140, PBARX2.75x75140, PBARX2.75x80140, PBARX2.75x85140, PBARX2.75x90140, PBARX2.75x95140, PBARX2.75x100140, PBARX2.75x150140, PBARX2.75x180140, PBARX2.75x200140, PBARX2.75x250140

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PBARX3.25x10140, PBARX3.25x15140, PBARX3.25x20140, PBARX3.25x25140, PBARX3.25x30140, PBARX3.25x35140, PBARX3.25x40140, PBARX3.25x45140, PBARX3.25x50140, PBARX3.25x55140, PBARX3.25x60140, PBARX3.25x65140, PBARX3.25x70140, PBARX3.25x75140, PBARX3.25x80140, PBARX3.25x85140, PBARX3.25x90140, PBARX3.25x95140, PBARX3.25x100140, PBARX3.25x150140, PBARX3.25x180140, PBARX3.25x200140, PBARX3.25x250140

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PBARX3.75x10140, PBARX3.75x15140, PBARX3.75x20140, PBARX3.75x25140, PBARX3.75x30140, PBARX3.75x35140, PBARX3.75x40140, PBARX3.75x45140, PBARX3.75x50140, PBARX3.75x55140, PBARX3.75x60140, PBARX3.75x65140, PBARX3.75x70140, PBARX3.75x75140, PBARX3.75x80140, PBARX3.75x85140, PBARX3.75x90140, PBARX3.75x95140, PBARX3.75x100140, PBARX3.75x150140, PBARX3.75x180140, PBARX3.75x200140, PBARX3.75x250140

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PBARX5.0x10140, PBARX5.0x15140, PBARX5.0x20140, PBARX5.0x25140, PBARX5.0x30140, PBARX5.0x35140, PBARX5.0x40140, PBARX5.0x45140, PBARX5.0x50140, PBARX5.0x55140, PBARX5.0x60140, PBARX5.0x65140, PBARX5.0x70140, PBARX5.0x75140, PBARX5.0x80140, PBARX5.0x85140, PBARX5.0x90140, PBARX5.0x95140, PBARX5.0x100140, PBARX5.0x150140, PBARX5.0x180140, PBARX5.0x200140, PBARX5.0x250140

PBARX5.5x10140, PBARX5.5x15140, PBARX5.5x20140, PBARX5.5x25140, PBARX5.5x30140, PBARX5.5x35140, PBARX5.5x40140, PBARX5.5x45140, PBARX5.5x50140, PBARX5.5x55140, PBARX5.5x60140, PBARX5.5x65140, PBARX5.5x70140, PBARX5.5x75140, PBARX5.5x80140, PBARX5.5x85140, PBARX5.5x90140, PBARX5.5x95140, PBARX5.5x100140, PBARX5.5x150140, PBARX5.5x180140, PBARX5.5x200140, PBARX5.5x250140

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PBARX6.5x10140, PBARX6.5x15140, PBARX6.5x20140, PBARX6.5x25140, PBARX6.5x30140, PBARX6.5x35140, PBARX6.5x40140, PBARX6.5x45140, PBARX6.5x50140, PBARX6.5x55140, PBARX6.5x60140, PBARX6.5x65140, PBARX6.5x70140, PBARX6.5x75140, PBARX6.5x80140, PBARX6.5x85140, PBARX6.5x90140, PBARX6.5x95140, PBARX6.5x100140, PBARX6.5x150140, PBARX6.5x180140, PBARX6.5x200140, PBARX6.5x250140

PBARX7.0x10140, PBARX7.0x15140, PBARX7.0x20140, PBARX7.0x25140, PBARX7.0x30140, PBARX7.0x35140, PBARX7.0x40140, PBARX7.0x45140, PBARX7.0x50140, PBARX7.0x55140, PBARX7.0x60140, PBARX7.0x65140, PBARX7.0x70140, PBARX7.0x75140, PBARX7.0x80140, PBARX7.0x85140, PBARX7.0x90140, PBARX7.0x95140, PBARX7.0x100140, PBARX7.0x150140, PBARX7.0x180140, PBARX7.0x200140, PBARX7.0x250140

Peripheral angioplasty catheter LOVIX, OVER THE WIRE type

Catalogue number	Nominal balloon diameter [mm]	Nominal balloon length [mm]	Use with guide - wire (symbol)	Catheter length [cm]
PBA1.5x201880, PBA1.5x2018100, PBA1.5x2018110, PBA1.5x2018120, PBA1.5x2018135, PBA1.5x2018170, PBA1.5x251880, PBA1.5x2518100, PBA1.5x2518110, PBA1.5x2518120, PBA1.5x2518135, PBA1.5x2518170, PBA1.5x301880, PBA1.5x3018100, PBA1.5x3018110, PBA1.5x3018120, PBA1.5x3018135, PBA1.5x3018170, PBA1.5x351880, PBA1.5x3518100, PBA1.5x3518110, PBA1.5x3518120, PBA1.5x3518135, PBA1.5x3518170, PBA1.5x401880, PBA1.5x4018100, PBA1.5x4018110, PBA1.5x4018120, PBA1.5x4018135, PBA1.5x4018170, PBA1.5x451880, PBA1.5x4518100, PBA1.5x4518110, PBA1.5x4518120, PBA1.5x4518135, PBA1.5x4518170, PBA1.5x501880, PBA1.5x5018100, PBA1.5x5018110, PBA1.5x5018120, PBA1.5x5018135, PBA1.5x5018170, PBA1.5x551880, PBA1.5x5518100, PBA1.5x5518110, PBA1.5x5518120, PBA1.5x5518135, PBA1.5x5518170, PBA1.5x601880, PBA1.5x6018100, PBA1.5x6018110, PBA1.5x6018120, PBA1.5x6018135, PBA1.5x6018170, PBA1.5x651880, PBA1.5x6518100, PBA1.5x6518110, PBA1.5x6518120, PBA1.5x6518135, PBA1.5x6518170, PBA1.5x701880, PBA1.5x7018100, PBA1.5x7018110, PBA1.5x7018120, PBA1.5x7018135, PBA1.5x7018170, PBA1.5x751880, PBA1.5x7518100, PBA1.5x7518110, PBA1.5x7518120, PBA1.5x7518135, PBA1.5x7518170, PBA1.5x801880, PBA1.5x8018100, PBA1.5x8018110, PBA1.5x8018120, PBA1.5x8018135,	B	C	E	H
	1.5, 2, 2.5, 3	20,25,30,35,40,45,50,55,60, 65,70,75,80,85,90,95,100	18	80, 100, 110, 120, 135, 170
		120, 150, 200, 250	25	
	4	20,25,30,35,40,45,50,55,60, 65,70,75,80,85,90,95,100	18	80, 100, 110, 120, 135, 170
		120, 150, 200, 250	25	
	5, 6	20,25,30,35,40,45,50,55,60, 65,70,75,80,85,90,95,100, 120	25	80, 100, 110, 120, 135, 170
		150, 200, 250	35	
	7	20,25,30,35,40,45,50,55,60,65,70,75,80,85,90,95,100, 120, 150,200, 250	35	80, 100, 110, 120, 135, 170
	8, 9, 10, 12, 14, 16	20,25,30,35,40,45,50,55,60, 65,70,75,80,85,90,95,100	35	80, 100, 110, 120, 135, 170

Reference:

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