

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:

Peripheral angioplasty catheter
LOVIX

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Peripheral angioplasty catheter	LOVIX	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.	PBAxBCD, PBARXxB140 where PBA= Peripheral Angioplasty Catheter, Over The Wire type PBARX= Peripheral Angioplasty Catheter, Rapid Exchange type (detailed list see annex)	IIb

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

ID number of the related audit report: 126-CE-190115-M04

Issue: 1

Issued: 25 March 2021

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Start date of certified status: 18 April 2017

Expires:

25 May 2024

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NB ID number: 2409



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

Valter PAPP, Dr.
General Manager



Peripheral angioplasty catheter LOVIX, OVER THE WIRE type


Catalogue number	Nominal balloon diameter r [mm]	Nominal balloon length [mm]	Use with guide wire		Catheter length [cm]
			Symbol	Size [cal]	
	B	C	E	F	H
PBABxCEH	1.5, 2, 2.5, 3	20,25,30,35,40,45,50,55,60, 65,70,75,80,85,90,95,100	18	.018"	80, 100,
			25	.025"	110, 120,
		120,150,200, 250	25	.025"	135, 170
PBABxCEH	4	20,25,30,35,40,45,50,55,60, 65,70,75,80,85,90,95,100	18	.018"	80,
			25	.025"	100,110,
			35	.035"	120, 135,
		120,150,200, 250	35	.035"	170
PBABxCEH	5, 6	20,25,30,35,40,45,50,55,60, 65,70,75,80,85,90,95,100, 120	25	.025"	80, 100,
			35	.035"	110, 120,
		150,200, 250	35	.035"	135, 170
PBABxCEH	7	20,25,30,35,40,45,50,55,60,65,70,75,80,85,90,95,100, 120, 150,200, 250	35	.035"	80, 100, 110, 120, 135, 170
PBABxCEH	8, 9, 10, 12, 14, 16	20,25,30,35,40,45,50,55,60, 65,70,75,80,85,90,95,100	35	.035"	80, 100, 110, 120, 135, 170

Peripheral angioplasty catheter LOVIX, RAPID EXCHANGE type

Calogue number	Nominal balloon diameter [mm]	Nominal balloon length [mm]
	B	C
PBARxBxC140	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

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