

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:

Paclitaxel coated peripheral angioplasty balloon catheter PAK

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Paclitaxel coated peripheral angioplasty balloon catheter	PAK	Indicated for improving luminal diameter in peripheral arterial lesions	PAKOTW „over the wire” (OTW) type, PAKRX “rapid exchange” (RX) type (See Annexes)	III*

*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 the 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

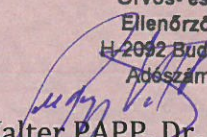
Start date of certified status: 30 May 2017

Expires:

25 May 2024

CE Certiso Kft.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecetiso.hu / www.cecetiso.hu
NB ID number: 2409




Valter PAPP, Dr.
General Manager

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



The certificate covers the following devices:

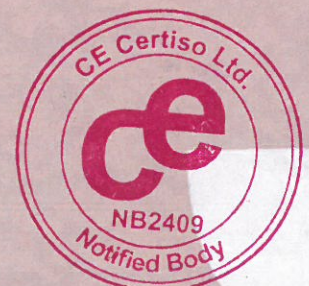
Paclitaxel coated peripheral angioplasty balloon catheter PAK OTW:

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

Issue: 1
Issued: 25 March 2021

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

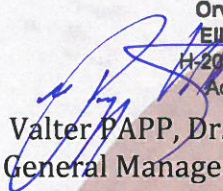
Valter PAPP, Dr.
General Manager



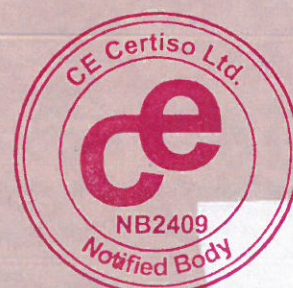
Paclitaxel coated peripheral angioplasty balloon catheter PAK RX

Calogue number	Nominal balloon diameter [mm]	Minimum Guiding Catheter I.D.	Nominal balloon length [mm]
	<i>E</i>	D	<i>G</i>
PAKRX <i>E</i> x <i>G</i> 140	1.25	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	1.50	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	1.75	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	2.00	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	2.25	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	2.50	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	2.75	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	3.00	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	3.25	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	3.50	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	3.75	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	4.00	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	4.50	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	5.00	.071"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	6.00	.071"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> x <i>G</i> 140	7.00	.088"	10, 15, 20, 25, 30, 35, 40

Issue: 1
Issued: 25 March 2021


Valter PAPP, Dr.
General Manager

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



EC DESIGN-EXAMINATION CERTIFICATE**Directive 93/42/EEC on Medical devices, Annex II (4)**

CE Certiso Ltd. (NB 2409) certifies that the design of the device concerning to the listed devices and device categories conforms to the 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:

Paclitaxel coated peripheral angioplasty balloon catheter PAK

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Paclitaxel coated peripheral angioplasty balloon catheter	PAK	Indicated for improving luminal diameter in peripheral arterial lesions	PAKOTW „over the wire” (OTW) type, PAKRX “rapid exchange” (RX) type (See Annexes)	III*

*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 the annexes and the system certificate No. **145091-21-03-25**, in case of successfully conducted annual surveillance audits.

ID number of the related design examination report: 126-G06-190115

Issue: 1

Issued: 25 March 2021

First issued: 25 March 2021

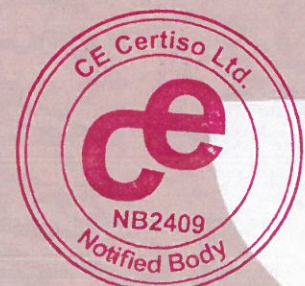
Start date of certified status: 30 May 2017

Expires:

25 May 2024**CE Certiso**

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

Valter PAPP, Dr.
General Manager



The certificate covers the following devices:

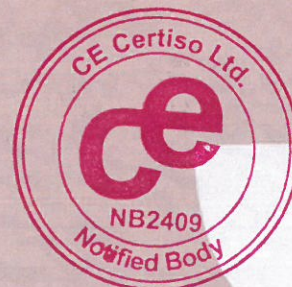
Paclitaxel coated peripheral angioplasty balloon catheter PAK OTW:

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

Issue: 1
Issued: 25 March 2021

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

Valter PAPP, Dr.
General Manager



Paclitaxel coated peripheral angioplasty balloon catheter PAK RX

Calogue number	Nominal balloon diameter [mm]	Minimum Guiding Catheter I.D.	Nominal balloon length [mm]
	<i>E</i>	D	<i>G</i>
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	1.25	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	1.50	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	1.75	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	2.00	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	2.25	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	2.50	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	2.75	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	3.00	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	3.25	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	3.50	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	3.75	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	4.00	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	4.50	.066"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	5.00	.071"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	6.00	.071"	10, 15, 20, 25, 30, 35, 40
PAKRX <i>E</i> <i>x</i> <i>G</i> 140	7.00	.088"	10, 15, 20, 25, 30, 35, 40

Issue: 1
Issued: 25 March 2021


Valter PAPP, Dr.
General Manager

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