By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

Digitally signed by Captari Alexandru
Date: 2022.11.08 13:58:19 EET
Reason: MoldSign Signature
Location: Moldova

This is to certify that:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Facility ID Number: F000099

Holds Certificate No: **MDSAP 688646**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture, and distribution of the following sterile devices: PTCA balloon catheters, PTA balloon catheters, drugreleasing PTCA balloon catheters, drug-releasing PTA balloon catheters, coronary stents and stent systems, peripheral stents and stent systems, drugeluting coronary stents and stent systems, coronary guidewires, peripheral guidewires, drug-eluting resorbable coronary scaffolds and scaffold systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-11 Effective Date: 2021-10-11 Expiry Date: 2024-10-10

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 608280**

Issued To: **BIOTRONIK AG**
Ackerstrasse 6
8180 Bülach
Switzerland

In respect of:

Design and manufacture of PTCA balloon catheters, PTA balloon catheters, drug-releasing PTCA balloon catheters, drug-releasing PTA balloon catheters, coronary stent systems, peripheral vascular stent systems, drug-eluting coronary stent systems, drug-eluting resorbable coronary scaffold systems, coronary guidewires and peripheral guidewires

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-04-01** Date: **2019-10-30** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 608280

Issued To:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Number	Device Name	Intended purpose per IFU
Class III		
---	Magmaris Sirolimus-Eluting Resorbable Coronary Magnesium Scaffold System	See CE 608221
	PRO-Kinetic Energy Coronary Stent System	See CE 608282
	Pantera LEO Fast-Exchange PTCA catheter	See CE 608283
	Orsiro Sirolimus-Eluting Coronary Stent System	See CE 608284
	Pantera Lux Paclitaxel releasing PTCA Balloon Catheter	See CE 608285
	PK Papyrus Covered Coronary Stent System	See CE 608286
	Synsiro Sirolimus-Eluting Coronary Stent System	See CE 608289
	Passeo-18 Lux Paclitaxel releasing PTA Balloon Catheter	See CE 610590
	Cruiser and Cruiser Hydro coronary and peripheral artery guidewires	See CE 619676
	Pantera Pro Coronary Dilatation Catheter	See CE 620197
	Orsiro Mission Sirolimus Eluting Coronary Stent System	See CE 704680
	Synsiro Pro Sirolimus Eluting Coronary Stent System	See CE 708283

First Issued: **2014-04-01** Date: **2019-10-30** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 608280

Issued To:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Number	Device Name	Intended purpose per IFU
Class IIb		
47932	Self-expanding NiTi peripheral stents	For use in patients with atherosclerotic disease of the iliac arteries and for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA), e.g. residual stenosis and dissection.
		For use in patients with atherosclerotic disease of the femoral and infrapopliteal arteries and for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA), e.g residual stenosis and dissection.
		For use in patients with atherosclerotic disease of the superficial femoral, proximal popliteal and infrapopliteal arteries and for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA), e.g. residual stenosis and dissection.

First Issued: **2014-04-01** Date: **2019-10-30** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 608280

Issued To:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Number	Device Name	Intended purpose per IFU
Class IIb		
47932	Balloon-expandable Cobalt Chromium peripheral stents	To improve sub-optimal angiographic results (≥ 50% residual stenosis) and/or flow-limiting dissections after PTA of atherosclerotic lesions in the infrapopliteal arteries.
44279	Iliac artery stents	For the treatment of de novo or restenotic atherosclerotic lesions in iliac arteries.
45852	Renal artery stents	For improving arterial luminal diameter in patients with clinical symptoms attributable to atherosclerotic stenosis of the renal arteries.
Class IIa		
MD 0106	PTA balloon catheters	---

First Issued: **2014-04-01** Date: **2019-10-30** Expiry Date: **2024-05-26**

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EC-Declaration of Conformity

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DOC No. 15-02-02 Issue: 10

Manufacturer:	Biotronik AG Ackerstrasse 6 8180 Bülach Switzerland	Authorised Representative:	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin Germany

Product Category:	PTCA balloon catheter
Product Name:	Pantera Pro Coronary Dilatation Catheter
Class:	III, according to Council Directive 93/42/EEC, Annex IX, rule 6
Conformity Assessment Route:	Council Directive 93/42/EEC, Annex II, Section 3 and 4
Scope:	33 different variants. See list on next pages

We hereby declare that the above-mentioned products meet the provisions of Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

For these products the following EC-Design Examination Certificate has been issued:

Certificate Number:	CE 620197
Notified Body:	BSI Group The Netherlands B.V.
EEC No:	2797
Expiry date:	26.MAY.2024

To these products our approved Full Quality Assurance System according to Annex II of the Directive 93/42/EEC is applied. For this Quality Assurance System, the following certificate has been issued:

Certificate Number:	CE 608280
Notified Body:	BSI Group The Netherlands B.V.
EEC No:	2797
Expiry date:	26.MAY.2024

Date of first CE-marking: 30.JAN.2015

Place, Date of issue: Bülach, 21.MAY.2021

Signature:

Marcel Schäfer, Ph.D.
Senior Director Regulatory Affairs and Post Market Surveillance

A11 REG 147074 EN 06

Scope of DoC No. 15-02-02

Pos.	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
1	Pantera Pro 1.25/6	393289	1.25	6	140
2	Pantera Pro 1.5/6	393290	1.5	6	140
3	Pantera Pro 1.25/10	393291	1.25	10	140
4	Pantera Pro 1.5/10	393292	1.5	10	140
5	Pantera Pro 2.0/10	393293	2.0	10	140
6	Pantera Pro 2.5/10	393294	2.5	10	140
7	Pantera Pro 3.0/10	393295	3.0	10	140
8	Pantera Pro 3.5/10	393296	3.5	10	140
9	Pantera Pro 4.0/10	393297	4.0	10	140
10	Pantera Pro 1.25/15	393298	1.25	15	140
11	Pantera Pro 1.5/15	393299	1.5	15	140
12	Pantera Pro 2.0/15	393300	2.0	15	140
13	Pantera Pro 2.5/15	393301	2.5	15	140
14	Pantera Pro 3.0/15	393302	3.0	15	140
15	Pantera Pro 3.5/15	393303	3.5	15	140
16	Pantera Pro 4.0/15	393304	4.0	15	140
17	Pantera Pro 1.25/20	393305	1.25	20	140
18	Pantera Pro 1.5/20	393306	1.5	20	140
19	Pantera Pro 2.0/20	393307	2.0	20	140
20	Pantera Pro 2.5/20	393308	2.5	20	140
21	Pantera Pro 3.0/20	393309	3.0	20	140
22	Pantera Pro 3.5/20	393310	3.5	20	140
23	Pantera Pro 4.0/20	393311	4.0	20	140
24	Pantera Pro 2.0/25	393312	2.0	25	140
25	Pantera Pro 2.5/25	393313	2.5	25	140
26	Pantera Pro 3.0/25	393314	3.0	25	140
27	Pantera Pro 3.5/25	393315	3.5	25	140
28	Pantera Pro 4.0/25	393316	4.0	25	140
29	Pantera Pro 2.0/30	393317	2.0	30	140
30	Pantera Pro 2.5/30	393318	2.5	30	140
31	Pantera Pro 3.0/30	393319	3.0	30	140
32	Pantera Pro 3.5/30	393320	3.5	30	140
33	Pantera Pro 4.0/30	393321	4.0	30	140

Change History

Version of SAP Document	Main changes from previous release to current release
01	New document using current template. Replaces "Pantera Pro_DOC_15_02_02_Issue4_REC142883_EN_01". New issue of EC Design -Examination Certificate.
02	New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
03	New issue due to sterilizer addition
04	Declaration of Conformity updated with the new expiry date of the EC Full Quality Assurance System Certificate
05	Declaration of Conformity updated with the new expiry date of the EC Design - Examination Certificate and using current template
06	Designation of Authorised (EU) Representative. Addition of name and address.

BIOTRONIK // Vascular Intervention

VI Product Catalogue

Oct 2021

- Coronary Products
- Peripheral Products
- Accessory Products

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5 Balloon Catheters

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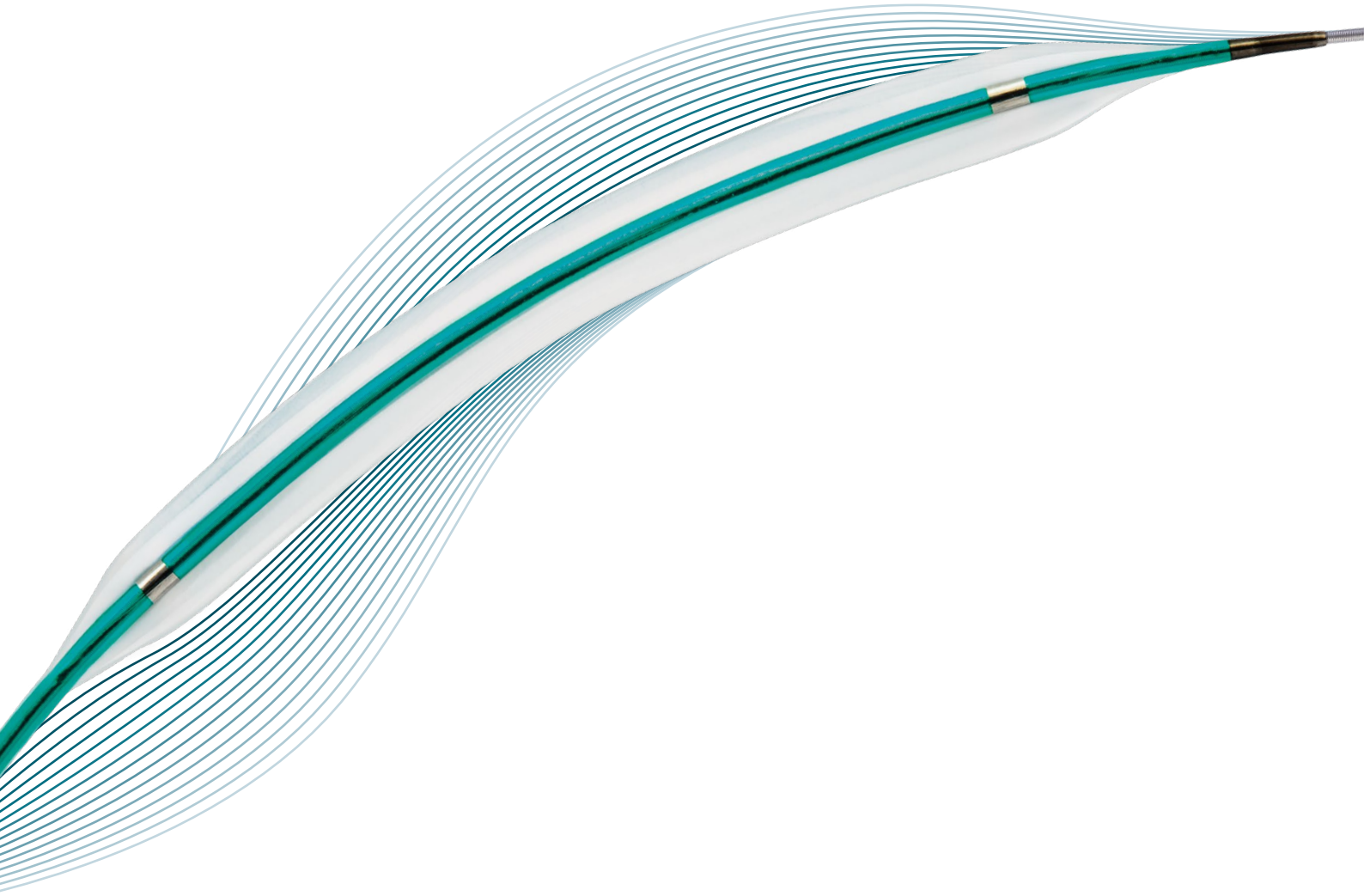
Vascular Intervention // Coronary
Semi-Compliant Workhorse Balloon Catheter

Pantera® Pro



- Lowest crossability in tight lesions
- 43% less friction during kissing balloon technique
- 38% more push to reach target lesion

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Pantera® Pro

Indicated for dilatation of coronary artery or bypass graft stenosis.*

Vascular
Intervention
Coronary

Technical Data

Proximal shaft	
Design	Hypotube design
Diameter	2.0F
Shaft markers	92 cm and 102 cm from tip

Distal shaft	
Guiding catheter	5F (min. I.D. 0.056" / 1.42 mm)
Guide wire diameter	0.014"
Lesion entry profile	0.017"
Usable length	140 cm
Balloon material	Semi Crystalline Co-Polymer
Balloon folding	ø 1.25 - 1.5 mm: Two-fold; ø 2.0 - 4.0 mm: Tri-fold
Balloon markers	Platinum-Iridium: ø 1.25 - 1.5 mm one marker; ø 2.0 - 4.0 mm two markers
Coating distal shaft	Hydrophilic (end of balloon to Guide Wire (GW) exit port)
Balloon and tip coating	ø 1.25 - 2.0 mm: Hydrophilic ø 2.50 - 4.0 mm: Hydrophobic
Kissing balloon technique	6F guiding catheter (min. I.D. 0.070" / 1.78 mm), up to ø 3.5 mm
Diameter	2.6F (ø 1.25 - 2.0 mm); 2.7F (ø 2.5 - 3.5 mm); 2.9F (ø 4.0 mm)

Compliance Chart

Balloon diameter x length (mm)

		ø 1.25 x 6-20	ø 1.50 x 6-20	ø 2.00 x 10-30	ø 2.50 x 10-30	ø 3.00 x 10-30	ø 3.50 x 10-30	ø 4.00 x 10-30
Nominal Pressure (NP)	atm**	7	7	7	7	7	7	7
	ø (mm)	1.24	1.49	2.01	2.49	3.08	3.62	3.95
Rated Burst Pressure (RBP)	atm**	14	14	14	14	14	14	14
	ø (mm)	1.37	1.72	2.23	2.93	3.50	4.06	4.55

**1 atm = 1.013 bar

Ordering Information

Balloon ø (mm)	Catheter length 140 cm Balloon length (mm)					
	6	10	15	20	25	30
1.25	393289	393291	393298	393305	-	-
1.50	393290	393292	393299	393306	-	-
2.00	-	393293	393300	393307	393312	393317
2.50	-	393294	393301	393308	393313	393318
3.00	-	393295	393302	393309	393314	393319
3.50	-	393296	393303	393310	393315	393320
4.00	-	393297	393304	393311	393316	393321

5F

*Indication as per IFU.

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