By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Digitally signed by Captari Alexandru
Date: 2022.02.21 10:22:29 EET
Reason: MoldSign Signature
Location: Moldova

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. 10-01-01 Issue: 11

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 LEO Fast-Exchange PTCA 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:	55 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 608283
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: 16.JAN.2010

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

Signature:

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

A11 REG 151459 EN 05

Scope of DoC No. 10-01-01

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]
1	Pantera LEO 2.0/8	366991	2.0	8
2	Pantera LEO 2.25/8	366992	2.25	8
3	Pantera LEO 2.5/8	366993	2.5	8
4	Pantera LEO 2.75/8	366994	2.75	8
5	Pantera LEO 3.0/8	366995	3.0	8
6	Pantera LEO 3.25/8	366996	3.25	8
7	Pantera LEO 3.5/8	366997	3.5	8
8	Pantera LEO 3.75/8	366998	3.75	8
9	Pantera LEO 4.0/8	366999	4.0	8
10	Pantera LEO 4.5/8	367000	4.5	8
11	Pantera LEO 5.0/8	367001	5.0	8
12	Pantera LEO 2.0/12	367002	2.0	12
13	Pantera LEO 2.25/12	367003	2.25	12
14	Pantera LEO 2.5/12	367004	2.5	12
15	Pantera LEO 2.75/12	367005	2.75	12
16	Pantera LEO 3.0/12	367006	3.0	12
17	Pantera LEO 3.25/12	367007	3.25	12
18	Pantera LEO 3.5/12	367008	3.5	12
19	Pantera LEO 3.75/12	367009	3.75	12
20	Pantera LEO 4.0/12	367010	4.0	12
21	Pantera LEO 4.5/12	367011	4.5	12
22	Pantera LEO 5.0/12	367012	5.0	12
23	Pantera LEO 2.0/15	367013	2.0	15
24	Pantera LEO 2.25/15	367014	2.25	15
25	Pantera LEO 2.5/15	367015	2.5	15
26	Pantera LEO 2.75/15	367016	2.75	15
27	Pantera LEO 3.0/15	367017	3.0	15
28	Pantera LEO 3.25/15	367018	3.25	15
29	Pantera LEO 3.5/15	367019	3.5	15
30	Pantera LEO 3.75/15	367020	3.75	15
31	Pantera LEO 4.0/15	367021	4.0	15
32	Pantera LEO 4.5/15	367022	4.5	15
33	Pantera LEO 5.0/15	367023	5.0	15

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]
34	Pantera LEO 2.0/20	367024	2.0	20
35	Pantera LEO 2.25/20	367025	2.25	20
36	Pantera LEO 2.5/20	367026	2.5	20
37	Pantera LEO 2.75/20	367027	2.75	20
38	Pantera LEO 3.0/20	367028	3.0	20
39	Pantera LEO 3.25/20	367029	3.25	20
40	Pantera LEO 3.5/20	367030	3.5	20
41	Pantera LEO 3.75/20	367031	3.75	20
42	Pantera LEO 4.0/20	367032	4.0	20
43	Pantera LEO 4.5/20	367033	4.5	20
44	Pantera LEO 5.0/20	367034	5.0	20
45	Pantera LEO 2.0/30	367035	2.0	30
46	Pantera LEO 2.25/30	367036	2.25	30
47	Pantera LEO 2.5/30	367037	2.5	30
48	Pantera LEO 2.75/30	367038	2.75	30
49	Pantera LEO 3.0/30	367039	3.0	30
50	Pantera LEO 3.25/30	367040	3.25	30
51	Pantera LEO 3.5/30	367041	3.5	30
52	Pantera LEO 3.75/30	367042	3.75	30
53	Pantera LEO 4.0/30	367043	4.0	30
54	Pantera LEO 4.5/30	367044	4.5	30
55	Pantera LEO 5.0/30	367045	5.0	30

Change History

Version of SAP Document	Main changes from previous release to current release
01	New document using current template. Replaces "Pantera LEO 10-01-01 Issue 6". New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
02	New issue due to sterilizer addition
03	Declaration of Conformity updated with the new expiry date of the EC Full Quality Assurance System Certificate
04	Declaration of Conformity updated with the new expiry date of the EC Design - Examination Certificate and using current template
05	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

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DOC No. 15-08-28 Issue: 5

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

Product Category:	Peripheral vascular stent system
Product Name:	Astron peripheral self-expanding Nitinol stent system
Class:	IIb, according to Council Directive 93/42/EEC, Annex IX, rule 8
Conformity Assessment Route:	Council Directive 93/42/EEC, Annex II, Section 3
Scope:	27 different variants. See list on next page.

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.

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: 28.AUG.2015

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

Signature:

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

A11 REG 151636 EN 03

Scope of DoC No. 15-08-28

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Usable length [cm]
1	Astron 7/30/70	343773	7	30	70
2	Astron 7/40/70	343774	7	40	70
3	Astron 7/60/70	343775	7	60	70
4	Astron 7/80/70	343776	7	80	70
5	Astron 8/30/70	343777	8	30	70
6	Astron 8/40/70	343778	8	40	70
7	Astron 8/60/70	343779	8	60	70
8	Astron 8/80/70	343780	8	80	70
9	Astron 9/30/70	343781	9	30	70
10	Astron 9/40/70	343782	9	40	70
11	Astron 9/60/70	343783	9	60	70
12	Astron 9/80/70	343784	9	80	70
13	Astron 7/30/120	343785	7	30	120
14	Astron 7/40/120	343786	7	40	120
15	Astron 7/60/120	343787	7	60	120
16	Astron 7/80/120	343788	7	80	120
17	Astron 8/30/120	343789	8	30	120
18	Astron 8/40/120	343790	8	40	120
19	Astron 8/60/120	343791	8	60	120
20	Astron 8/80/120	343792	8	80	120
21	Astron 9/30/120	343793	9	30	120
22	Astron 9/40/120	343794	9	40	120
23	Astron 9/60/120	343795	9	60	120
24	Astron 9/80/120	343796	9	80	120
25	Astron 10/40/70	349214	10	40	70
26	Astron 10/60/70	349215	10	60	70
27	Astron 10/80/70	349216	10	80	70

Change History

Version of SAP Document	Main changes from previous release to current release
01	New Document using current template. Replaces "Astron DOC 150828 Issue 2". Transfer of Notified Body to BSI Group The Netherlands B.V.
02	Declaration of Conformity updated with the new expiry date of the EC Full Quality Assurance System Certificate.
03	Designation of Authorised (EU) Representative. Addition of name and address.