

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

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



BSI Group America Inc. is an MDSAP authorized auditing organization

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# 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: **2021-05-14**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# 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
<b>Class III</b>		
---	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

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Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
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.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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**Ackerstrasse 6**  
**8180 Bülach**  
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Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
47932	Balloon-expandable Cobalt Chromium peripheral stents	To improve sub-optimal angiographic results ( $\geq 50\%$ 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.
<b>Class IIa</b>		
MD 0106	PTA balloon catheters	---

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