By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

DUNS Number: 48-086-2817

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 [if design controls are part of the certification]; 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, distribution and sterilization of 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:

Carlos Pitanga, Chief Operating Officer Assurance - Americas

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

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

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Digitally signed by Captari Alexandru
Date: 2021.09.07 21:29:32 EEST
Reason: MoldSign Signature
Location: Moldova

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

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. 13-06-02 Issue: 11

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

Product Category:	Coronary stent system
Product Name:	PK Papyrus Covered Coronary Stent System
Class:	III, according to Council Directive 93/42/EEC, Annex IX, rule 8
Conformity Assessment Route:	Council Directive 93/42/EEC, Annex II, Section 3 and 4
Scope:	17 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.

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

Certificate Number:	CE 608286
Notified Body:	BSI Group The Netherlands B.V.
EEC No:	2797
Expiry date:	10.Jun.2023

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: 12.Jun.2013

Place, Date of issue: Bülach, 21.MAY.201

Signature:

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

A11 REG 146249 EN 06

Scope of DoC No. 13-06-02

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]
1	PK Papyrus 2.5/15	369380	2.5	15
2	PK Papyrus 3.0/15	369381	3.0	15
3	PK Papyrus 3.5/15	369382	3.5	15
4	PK Papyrus 4.0/15	369383	4.0	15
5	PK Papyrus 4.5/15	369384	4.5	15
6	PK Papyrus 5.0/15	369385	5.0	15
7	PK Papyrus 2.5/20	369386	2.5	20
8	PK Papyrus 3.0/20	369387	3.0	20
9	PK Papyrus 3.5/20	369388	3.5	20
10	PK Papyrus 4.0/20	369389	4.0	20
11	PK Papyrus 4.5/20	369390	4.5	20
12	PK Papyrus 5.0/20	369391	5.0	20
13	PK Papyrus 3.0/26	381789	3.0	26
14	PK Papyrus 3.5/26	381790	3.5	26
15	PK Papyrus 4.0/26	381791	4.0	26
16	PK Papyrus 4.5/26	369392	4.5	26
17	PK Papyrus 5.0/26	369393	5.0	26

Change History

Check version index is up to date prior to use.

Version of SAP Document	Main changes from previous release to current release
01	New Document using current template. Replaces "PK Papyrus 130602 Issue 5".
02	Declaration of Conformity updated with the new expiry date of the EC Design Examination Certificate.
03	New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
04	New issue due to sterilizer addition.
05	Declaration of Conformity updated with the new expiry date of the EC Full Quality Assurance System Certificate.
06	Designation of Authorised (EU) Representative. Addition of name and address.

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.

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

BIOTRONIK
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DOC No. 11-02-01 Issue: 18

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

Product Category:	Drug-eluting stents for vascular intervention
Product Name:	Orsiro Sirolimus Eluting Coronary Stent System
Class:	III, according to Council Directive 93/42/EEC, Annex IX, rule 8 and 13
Conformity Assessment Route:	Council Directive 93/42/EEC, Annex II, Section 3 and 4
Scope:	54 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 608284
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:	25.FEB.2011
Place, Date of issue:	Bülach, 21.MAY.2021

Signature:

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

A11 REG 151631 EN 07

Scope of DoC No. 11-02-01

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Nominal Total Drug Load TDL [µg]
1	Orsiro 2.25/9	364469	2.25	9	55
2	Orsiro 2.5/9	364470	2.5	9	55
3	Orsiro 2.75/9	364471	2.75	9	55
4	Orsiro 3.0/9	364472	3.0	9	55
5	Orsiro 3.5/9	364473	3.5	9	70
6	Orsiro 4.0/9	364474	4.0	9	70
7	Orsiro 2.25/13	364475	2.25	13	80
8	Orsiro 2.5/13	364476	2.5	13	80
9	Orsiro 2.75/13	364477	2.75	13	80
10	Orsiro 3.0/13	364478	3.0	13	80
11	Orsiro 3.5/13	364479	3.5	13	95
12	Orsiro 4.0/13	364480	4.0	13	95
13	Orsiro 2.25/15	364481	2.25	15	93
14	Orsiro 2.5/15	364482	2.5	15	93
15	Orsiro 2.75/15	364483	2.75	15	93
16	Orsiro 3.0/15	364484	3.0	15	93
17	Orsiro 3.5/15	364485	3.5	15	113
18	Orsiro 4.0/15	364486	4.0	15	113
19	Orsiro 2.25/18	364487	2.25	18	109
20	Orsiro 2.5/18	364488	2.5	18	109
21	Orsiro 2.75/18	364489	2.75	18	109
22	Orsiro 3.0/18	364490	3.0	18	109
23	Orsiro 3.5/18	364491	3.5	18	131
24	Orsiro 4.0/18	364492	4.0	18	131
25	Orsiro 2.25/22	364499	2.25	22	134
26	Orsiro 2.5/22	364500	2.5	22	134
27	Orsiro 2.75/22	364501	2.75	22	134
28	Orsiro 3.0/22	364502	3.0	22	134
29	Orsiro 3.5/22	364503	3.5	22	162
30	Orsiro 4.0/22	364504	4.0	22	162
31	Orsiro 2.25/26	364505	2.25	26	159
32	Orsiro 2.5/26	364506	2.5	26	159
33	Orsiro 2.75/26	364507	2.75	26	159
34	Orsiro 3.0/26	364508	3.0	26	159
35	Orsiro 3.5/26	364509	3.5	26	193
36	Orsiro 4.0/26	364510	4.0	26	193
37	Orsiro 2.25/30	364511	2.25	30	184
38	Orsiro 2.5/30	364512	2.5	30	184
39	Orsiro 2.75/30	364513	2.75	30	184
40	Orsiro 3.0/30	364514	3.0	30	184
41	Orsiro 3.5/30	364515	3.5	30	224
42	Orsiro 4.0/30	364516	4.0	30	224
43	Orsiro 2.25/35	391234	2.25	35	213

44	Orsiro 2.5/35	391235	2.5	35	213
45	Orsiro 2.75/35	391236	2.75	35	213
46	Orsiro 3.0/35	391237	3.0	35	213
47	Orsiro 3.5/35	391018	3.5	35	261
48	Orsiro 4.0/35	391019	4.0	35	261
49	Orsiro 2.25/40	391238	2.25	40	247
50	Orsiro 2.5/40	391239	2.5	40	247
51	Orsiro 2.75/40	391240	2.75	40	247
52	Orsiro 3.0/40	391241	3.0	40	247
53	Orsiro 3.5/40	391020	3.5	40	298
54	Orsiro 4.0/40	391021	4.0	40	298

Change History

Check version index is up to date prior to use.

Version of SAP Document	Main changes from previous release to current release
01	Transfer from previous template to new template TMP 111387. New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
02	New issue due to sterilizer addition
03	Revised for the introduction of the electronic IFU in compliance with regulation 207/2012.
04	Declaration of Conformity updated with the new expiry date of the EC Full Quality Assurance System Certificate
05	Implementation of the recertification
06	New issue due to changes affecting Sirolimus at supplier Biocon Limited (heavy metals in specification; test methods for particle size and residual solvent; and re-test period).
07	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

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DOC No. **04-12-01** Issue: 11

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:	Dynamic Peripheral Stent and Delivery 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:	38 different variants. *See list on next page 2*

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: 23.DEC.2004

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

Signature:

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

A11 REG 151638 EN 03

Scope of DoC No. 04-12-01

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Usable length [cm]
1	Dynamic 5/15/80	350110	5	15	80
2	Dynamic 6/15/80	350111	6	15	80
3	Dynamic 7/15/80	350112	7	15	80
4	Dynamic 8/15/80	350113	8	15	80
5	Dynamic 5/25/80	350114	5	25	80
6	Dynamic 6/25/80	350115	6	25	80
7	Dynamic 7/25/80	350116	7	25	80
8	Dynamic 8/25/80	350117	8	25	80
9	Dynamic 9/25/80	350118	9	25	80
10	Dynamic 10/25/80	350119	10	25	80
11	Dynamic 5/38/80	350120	5	38	80
12	Dynamic 6/38/80	350121	6	38	80
13	Dynamic 7/38/80	350122	7	38	80
14	Dynamic 8/38/80	350123	8	38	80
15	Dynamic 9/38/80	350124	9	38	80
16	Dynamic 10/38/80	350125	10	38	80
17	Dynamic 5/56/80	350126	5	56	80
18	Dynamic 6/56/80	350127	6	56	80
19	Dynamic 7/56/80	350128	7	56	80
20	Dynamic 8/56/80	350129	8	56	80
21	Dynamic 9/56/80	350130	9	56	80
22	Dynamic 10/56/80	350131	10	56	80
23	Dynamic 5/15/130	350132	5	15	130
24	Dynamic 6/15/130	350133	6	15	130
25	Dynamic 7/15/130	350134	7	15	130
26	Dynamic 8/15/130	350135	8	15	130
27	Dynamic 5/25/130	350136	5	25	130
28	Dynamic 6/25/130	350137	6	25	130
29	Dynamic 7/25/130	350138	7	25	130
30	Dynamic 8/25/130	350139	8	25	130
31	Dynamic 5/38/130	350140	5	38	130
32	Dynamic 6/38/130	350141	6	38	130
33	Dynamic 7/38/130	350142	7	38	130
34	Dynamic 8/38/130	350143	8	38	130
35	Dynamic 5/56/130	350144	5	56	130
36	Dynamic 6/56/130	350145	6	56	130
37	Dynamic 7/56/130	350146	7	56	130
38	Dynamic 8/56/130	350147	8	56	130

Change History

Version of SAP Document	Main changes from previous release to current release
01	New document using current template. Replaces "Dynamic Renal_DoC_061101_issue8". New "Issue" number due to transfer of Notified Body to BSI Group The Netherlands B.V; having a new NB number.
02	Update to new template revision. New issue initiated by an update of the EC Full Quality Assurance System Certificate, having a new expiry date.
03	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

BIOTRONIK
excellence for life

DOC No. **06-11-01** Issue: 11

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:	Dynamic Renal - Renal 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:	24 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.

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: 10.NOV.2006

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

Signature:

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

A11 REG 151639 EN 03

Scope of DoC No. 06-11-01

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Usable length [cm]
1	Dynamic Renal 4.5/12/80	358574	4.5	12	80
2	Dynamic Renal 5.0/12/80	358575	5.0	12	80
3	Dynamic Renal 6.0/12/80	358576	6.0	12	80
4	Dynamic Renal 7.0/12/80	358577	7.0	12	80
5	Dynamic Renal 4.5/15/80	368707	4.5	15	80
6	Dynamic Renal 5.0/15/80	368708	5.0	15	80
7	Dynamic Renal 6.0/15/80	368709	6.0	15	80
8	Dynamic Renal 7.0/15/80	368710	7.0	15	80
9	Dynamic Renal 4.5/19/80	358578	4.5	19	80
10	Dynamic Renal 5.0/19/80	358579	5.0	19	80
11	Dynamic Renal 6.0/19/80	358580	6.0	19	80
12	Dynamic Renal 7.0/19/80	358581	7.0	19	80
13	Dynamic Renal 4.5/12/140	358582	4.5	12	140
14	Dynamic Renal 5.0/12/140	358583	5.0	12	140
15	Dynamic Renal 6.0/12/140	358584	6.0	12	140
16	Dynamic Renal 7.0/12/140	358585	7.0	12	140
17	Dynamic Renal 4.5/15/140	368711	4.5	15	140
18	Dynamic Renal 5.0/15/140	368712	5.0	15	140
19	Dynamic Renal 6.0/15/140	368713	6.0	15	140
20	Dynamic Renal 7.0/15/140	368714	7.0	15	140
21	Dynamic Renal 4.5/19/140	358586	4.5	19	140
22	Dynamic Renal 5.0/19/140	358587	5.0	19	140
23	Dynamic Renal 6.0/19/140	358588	6.0	19	140
24	Dynamic Renal 7.0/19/140	358589	7.0	19	140

Change History

Version of SAP Document	Main changes from previous release to current release
01	New document using current template. Replaces "Dynamic Renal_DoC_061101_issue8". New "Issue" number due to transfer of Notified Body to BSI Group The Netherlands B.V; having a new NB number.
02	Update to new template revision. New issue initiated by an update of the EC Full Quality Assurance System Certificate, having a new expiry date.
03	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

BIOTRONIK
excellence for life

DOC No. 07-04-01 Issue: 12

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

Product Category:	PTA balloon catheter
Product Name:	Passeo-35 Peripheral Dilatation Catheter
Class:	IIa, according to Council Directive 93/42/EEC, Annex IX, rule 6
Conformity Assessment Route:	Council Directive 93/42/EEC, Annex II, Section 3
Scope:	116 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.

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: 02.APR.2007

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

Signature:

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

A11 REG 151641 EN 04

Scope of DoC No. 07-04-01

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]]	Usable length [cm]
1	Passeo-35 3/20/80	359545	3	20	80
2	Passeo-35 4/20/80	359546	4	20	80
3	Passeo-35 5/20/80	357282	5	20	80
4	Passeo-35 6/20/80	357283	6	20	80
5	Passeo-35 7/20/80	357284	7	20	80
6	Passeo-35 8/20/80	357285	8	20	80
7	Passeo-35 9/20/80	357286	9	20	80
8	Passeo-35 10/20/80	357287	10	20	80
9	Passeo-35 3/40/80	359547	3	40	80
10	Passeo-35 4/40/80	359548	4	40	80
11	Passeo-35 5/40/80	357288	5	40	80
12	Passeo-35 6/40/80	357289	6	40	80
13	Passeo-35 7/40/80	357290	7	40	80
14	Passeo-35 8/40/80	357291	8	40	80
15	Passeo-35 9/40/80	357292	9	40	80
16	Passeo-35 10/40/80	357293	10	40	80
17	Passeo-35 5/60/80	357294	5	60	80
18	Passeo-35 6/60/80	357295	6	60	80
19	Passeo-35 7/60/80	357296	7	60	80
20	Passeo-35 8/60/80	357297	8	60	80
21	Passeo-35 5/80/80	357298	5	80	80
22	Passeo-35 6/80/80	357299	6	80	80
23	Passeo-35 7/80/80	357300	7	80	80
24	Passeo-35 8/80/80	357301	8	80	80
25	Passeo-35 5/100/80	357302	5	100	80
26	Passeo-35 6/100/80	357303	6	100	80
27	Passeo-35 7/100/80	357304	7	100	80
28	Passeo-35 8/100/80	357305	8	100	80
29	Passeo-35 3/20/130	359549	3	20	130
30	Passeo-35 4/20/130	359550	4	20	130
31	Passeo-35 5/20/130	357306	5	20	130
32	Passeo-35 6/20/130	357307	6	20	130
33	Passeo-35 7/20/130	357308	7	20	130
34	Passeo-35 8/20/130	357309	8	20	130
35	Passeo-35 3/40/130	359551	3	40	130
36	Passeo-35 4/40/130	359552	4	40	130
37	Passeo-35 5/40/130	357310	5	40	130
38	Passeo-35 6/40/130	357311	6	40	130
39	Passeo-35 7/40/130	357312	7	40	130
40	Passeo-35 8/40/130	357313	8	40	130

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]]	Usable length [cm]
41	Passeo-35 5/60/130	357314	5	60	130
42	Passeo-35 6/60/130	357315	6	60	130
43	Passeo-35 7/60/130	357316	7	60	130
44	Passeo-35 8/60/130	357317	8	60	130
45	Passeo-35 5/80/130	357318	5	80	130
46	Passeo-35 6/80/130	357319	6	80	130
47	Passeo-35 7/80/130	357320	7	80	130
48	Passeo-35 8/80/130	357321	8	80	130
49	Passeo-35 5/100/130	357322	5	100	130
50	Passeo-35 6/100/130	357323	6	100	130
51	Passeo-35 7/100/130	357324	7	100	130
52	Passeo-35 8/100/130	357325	8	100	130
53	Passeo-35 3/60/90	383231	3	60	90
54	Passeo-35 4/60/90	383232	4	60	90
55	Passeo-35 9/60/90	383233	9	60	90
56	Passeo-35 10/60/90	383234	10	60	90
57	Passeo-35 3/80/90	383235	3	80	90
58	Passeo-35 4/80/90	383236	4	80	90
59	Passeo-35 9/80/90	383237	9	80	90
60	Passeo-35 10/80/90	383238	10	80	90
61	Passeo-35 3/100/90	383239	3	100	90
62	Passeo-35 4/100/90	383240	4	100	90
63	Passeo-35 3/120/90	383243	3	120	90
64	Passeo-35 4/120/90	383244	4	120	90
65	Passeo-35 5/120/90	383245	5	120	90
66	Passeo-35 6/120/90	383246	6	120	90
67	Passeo-35 7/120/90	383247	7	120	90
68	Passeo-35 3/150/90	389775	3	150	90
69	Passeo-35 4/150/90	383248	4	150	90
70	Passeo-35 5/150/90	383249	5	150	90
71	Passeo-35 6/150/90	383250	6	150	90
72	Passeo-35 7/150/90	383251	7	150	90
73	Passeo-35 3/170/90	389776	3	170	90
74	Passeo-35 4/170/90	383252	4	170	90
75	Passeo-35 5/170/90	383253	5	170	90
76	Passeo-35 6/170/90	383254	6	170	90
77	Passeo-35 7/170/90	383255	7	170	90
78	Passeo-35 3/200/90	387162	3	200	90
79	Passeo-35 4/200/90	383256	4	200	90
80	Passeo-35 5/200/90	383257	5	200	90
81	Passeo-35 6/200/90	383258	6	200	90
82	Passeo-35 7/200/90	383259	7	200	90

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]]	Usable length [cm]
83	Passeo-35 9/20/130	383260	9	20	130
84	Passeo-35 10/20/130	383261	10	20	130
85	Passeo-35 9/40/130	383262	9	40	130
86	Passeo-35 10/40/130	383263	10	40	130
87	Passeo-35 3/60/130	383264	3	60	130
88	Passeo-35 4/60/130	383265	4	60	130
89	Passeo-35 9/60/130	383266	9	60	130
90	Passeo-35 10/60/130	383267	10	60	130
91	Passeo-35 3/80/130	383268	3	80	130
92	Passeo-35 4/80/130	383269	4	80	130
93	Passeo-35 9/80/130	383270	9	80	130
94	Passeo-35 10/80/130	383271	10	80	130
95	Passeo-35 3/100/130	383272	3	100	130
96	Passeo-35 4/100/130	383273	4	100	130
97	Passeo-35 3/120/130	383276	3	120	130
98	Passeo-35 4/120/130	383277	4	120	130
99	Passeo-35 5/120/130	383278	5	120	130
100	Passeo-35 6/120/130	383279	6	120	130
101	Passeo-35 7/120/130	383280	7	120	130
102	Passeo-35 3/150/130	389777	3	150	130
103	Passeo-35 4/150/130	383281	4	150	130
104	Passeo-35 5/150/130	383282	5	150	130
105	Passeo-35 6/150/130	383283	6	150	130
106	Passeo-35 7/150/130	383284	7	150	130
107	Passeo-35 3/170/130	389778	3	170	130
108	Passeo-35 4/170/130	383285	4	170	130
109	Passeo-35 5/170/130	383286	5	170	130
110	Passeo-35 6/170/130	383287	6	170	130
111	Passeo-35 7/170/130	383288	7	170	130
112	Passeo-35 3/200/130	387163	3	200	130
113	Passeo-35 4/200/130	383289	4	200	130
114	Passeo-35 5/200/130	383290	5	200	130
115	Passeo-35 6/200/130	383291	6	200	130
116	Passeo-35 7/200/130	383292	7	200	130

Change History

Check version index is up to date prior to use.

Version of SAP Document	Main changes from previous release to current release
01	Transfer to new template TMP111387. Replaces "DOC_070401_Passeo-35_Issue8". New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
02	Corrected to TMP 110093 and corrected CE 608280 expiry date to 2019-AUG-31.
03	Declaration of Conformity updated with the new expiry date of the EC Full Quality Assurance System Certificate.
04	Designation of Authorised (EU) Representative. Addition of name and address.

LNE
Le progrès, une passion à partager

Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION / *CERTIFICATE* **N° 10463 rev. 19**
Délivrée à Paris le 29 mai 2018
Issued in Paris on May 29th, 2018

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

ARTHESYS
4 rue René Razel
91400 SACLAY FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Cathéters d'angioplastie - Stent intravasculaire - Connecteur Y à valve - Accessoires pour procédures endovasculaires - Cathéters d'aspiration.

Angioplasty catheters - Intravascular stent - Y connector with valve - Accessories for endovascular procédures - Aspiration catheters.

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177739-1, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P177739-1, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **June 10th, 2018 (included)**
Valable jusqu'au / *Expiry date :* **June 9th, 2021 (included)**

Laboratoire national de métrologie et d'essais LNE

On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Director

LNE - 10463 rev. 19
Renouvelle le certificat 10463-18

GMED_N2b3-V3-01-2013

Le progrès, une passion à partager

Certification
Médical-Santé

Addendum au certificat n° 10463 rev. 19
Addendum of the certificate n° 10463 rev. 19
Dossier / *File* N° P177739-1

Identification des dispositifs / *Identification of devices*

Les produits couverts par ce certificat sont référencés sur la liste des produits authentifiée par le LNE/G-MED en date du 08 mars 2018 (19 pages)
The products covered by this certificate are listed on the list authenticated by LNE/G-MED on March 8th, 2018 (19 pages)

Ce certificat couvre les activités et le site suivant :
This certificate covers the following activities and site:

- **ARTHESYS – 4 rue René Razel - 91400 SACLAY FRANCE**
  Siège social – Activités de conception, de fabrication et contrôle final
  Headquarters – Design, manufacturing and final inspection activities

1 site / *1 location*

LNE/G-MED	0459

Laboratoire national de métrologie et d'essais • LNE

On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Director

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

GMED GROUPE LNE

ATTESTATION */ CERTIFICATE* **N° 23251 rev. 9**
Délivrée à Paris le 01 décembre 2020
Issued in Paris on December 1st, 2020

ATTESTATION CE */ EC CERTIFICATE*

Examen CE de la Conception (du produit) / EC Design Examination (of the product)
ANNEXE II point 4 de la directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II section 4 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant */ Manufacturer*

ARTHESYS
4 rue René Razel
91400 SACLAY FRANCE

Catégorie du(des) dispositif(s) */ Device(s) category*

Cathéter de Thrombo aspiration

Aspiration Catheter

Identification du(des) dispositif(s) */ Identification of device(s)*
3Flow Aspiration Catheter

3Flow Aspiration Catheter

Voir document complémentaire GMED / See GMED additional document
n° 37453

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P601489, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file(s) referenced P601489, the product(s) complie(s) with the requirements of the directive 93/42/EEC, annex 1

Début de validité */ Effective date :* **December 1st, 2020 (included)**
Valable jusqu'au */ Expiry date :* **May 26th, 2024 (included)**

DocuSigned by:
Béatrice LYS
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GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED - 23251 rev. 9
Modifie le certificat 23251-8

GMED_b2p4_new2020-V0-04-2020

Ce document complémentaire GMED n° 37453 rev. 0 atteste de la validité du certificat CE n° 23251 rev. 9 au regard des informations listées ci-dessous.

This GMED additional document n° 37453 rev. 0 attests to the validity of CE certificate n° 23251 rev. 9 with regard to the information listed below.

Fabricant / *Manufacturer:*

ARTHESYS
4 rue René Razel
91400 SACLAY FRANCE

Identification des dispositifs / *Identification of devices*

Désignation du dispositif	Référence	GMDN
3Flow Aspiration Catheter 6F	387456	58173
3Flow Aspiration Catheter 7F	387457	

GMED	0459

GMED – 37453 rev. 0

DocuSigned by:
Béatrice LYS
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

3 FLOW catheter ECD 05 20

EC Declaration of Conformity to Council Directive 93/42/EC amended by 2007/47/EC
(Full quality assurance system)

Manufacturer:	***ARTHESYS*** 4 Rue René Razel 91400 Saclay France
Device:	**3 FLOW catheter**
Family of Medical Device:	Aspiration catheter
Product Design Dossier reference:	TDR04030102
EC Product Class:	Class III according to Annex IX, Rule 6 of the Directive
Applicable certificate:	Certificates N°23251 rev.8
Product range:	cf table here enclosed
Notified body:	GMED 1, rue Gaston Boissier 75015 Paris France

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ARTHESYS declares that devices listed above conform to the relevant provisions of the EC Council Directive 2007/47/EC dated 5 September 2007 amending Council Directive 93/42/EC and are in accordance with Annex II Conformity Assessment Procedure and ISO 13485: 2016 registered Quality Management System as implemented by European Communities (Medical Devices), as verified by appointed Notified Body LNE/G-Med (0459).

ARTHESYS is continually developing, implementing and maintaining a formally recognized Quality Management System that ensures continued conformity and effectiveness.

ARTHESYS undertakes to develop, implement and maintain a documented post-market experience surveillance program, along with notification of incidents notifiable under the European Medical Device Vigilance system guidelines.

ARTHESYS confirms that:

☒ no substances that may be of animal origin are incorporated in any devices covered by the product schedule.

☒ no human blood derivatives, tissues or cells of human origin are incorporated in any devices covered by the product schedule.

☒ no medicinal products are incorporated in any devices covered by the product schedule.

ARTHESYS undertakes to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

This declaration is issued under the sole responsibility of the manufacturer.

General Director: Jean-Romuald BONNIN

Date: 14/05/2020

Signature:

3 FLOW catheter

3 FLOW catheter is manufactured in ARTHESYS, 4 rue René Razel, 91400 Saclay, France.

3 FLOW catheter product range is:

	ARTHESYS reference	BIOTRONIK reference
3 FLOW sterile 6F	04030241	387456
3 FLOW steril 7F	04030242	387457

Declaration of Conformity
Application of Council Directive 93/42/EEC, as amended by 2007/47/EC

Manufacturer:	Concert Medical, LLC 77 Accord Park Drive Norwell, MA 02061 Tel. (781) 871-7882 Fax (781) 871-6657 Tim Powers, VP Quality Assurance & Regulatory Affairs
European Authorized Representative:	Emergo Europe Prinsessegracht 20 2514 AP, The Hague The Netherlands Tel. (31) (0) 70 345-8570 Fax (31) (0) 70 345-8570
Name of Device(s):	Galeo Coronary Guidewires; Galeo Hydro Coronary Guidewires; Galeo Pro Coronary Guidewires
Device Catalog Number(s):	See list on page 2
Classification:	Class III (MDD Annex IX, Rule 6)
Notified Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium Tel. +32 (0)3 545-48-48 Fax +32 (0)3 545-48-49
EC Certificate No:	US19/819943619.02; US19/819943591.02
Date CE Mark was First Affixed:	13 January 2012
Declaration of Conformity Current Revision Date:	31 December 2019

Statement of Conformity:
I, the undersigned, hereby declare that the products specified above conform to Annex II of Council Directive 93/42/EEC of 14 June 1993, as Amended by 2007/47/EC, concerning medical devices.

Timothy S. Powers
Vice President, Quality Assurance & Regulatory Affairs

Concert Medical LIMITED LIABILITY COMPANY 2005 MASSACHUSETTS

List of Catalog Numbers:

389781 (Galeo Pro Guidewire High Flexible (HF) Straight Tip; 190 cm)
389783 (Galeo Pro Guidewire Flexible (F) Straight Tip; 190 cm)
389785 (Galeo Pro Guidewire Medium (M) Straight Tip; 190 cm)
389787 (Galeo Pro Guidewire Extra Support (ES) Straight Tip; 190 cm)
389782 (Galeo Pro Guidewire High Flexible (HF) J-Tip; 190 cm)
389784 (Galeo Pro Guidewire Flexible (F) J-Tip; 190 cm)
389786 (Galeo Pro Guidewire Medium (M) J-Tip; 190 cm)
389788 (Galeo Pro Guidewire Extra Support (ES) J-Tip; 190 cm)
389791 (Galeo Pro Guidewire Flexible (F) Straight Tip; 300 cm)
406886 (Galeo Guidewire High Flexible (HF) Tip; 190 cm)
406887 (Galeo Guidewire Flexible (F) Tip; 190 cm)
406888 (Galeo Guidewire Medium (M) Tip; 190 cm)
406889 (Galeo Guidewire Extra Support Flexible (ES-F) Tip; 190 cm)
406890 (Galeo EW Extension Wire)
406891 (Galeo Hydro Guidewire High Flexible (HF) Tip; 190 cm)
406892 (Galeo Hydro Guidewire Flexible (F) Tip; 190 cm)
406893 (Galeo Hydro Guidewire Medium (M) Tip; 190 cm)
406894 (Galeo Hydro Guidewire Extra Support Flexible (ES-F) Tip; 190 cm)