BIOTRONIK
excellence for life

TO WHOM IT MAY CONCERN

Biotronik AG
Ackerstrasse 6
CH-8180 Buelach
Switzerland

Tel +41 44 864 51 11
Fax +41 44 864 50 05
www.biotronik.com

Digitally signed by Captari Alexandru
Date: 2022.02.01 12:10:47 EET
Reason: MoldSign Signature
Location: Moldova

Bülach, January 27, 2022
CIS / 2022_334

Letter of Authorization
TENDER Nr. 21047377

We, Biotronik AG, Ackerstrasse 6, CH-8180 Buelach, Switzerland, a manufacturer of medical devices for Vascular Intervention, having plants in Switzerland, hereby permit **CAVATEH M SRL, MD-2028 Chisinau, Academiei 3 str., of. 110B, Republic of Moldova. (e-mail: cavateh@gmail.com, tel. +373-68-558-556)**, related **Tender Nr. 21047377** to non-exclusively sell on its own behalf and on its own account all the products manufactured by us throughout the **Republic of Moldova** and therefore confirm that it can negotiate and conclude according contracts on its own behalf and on its own account with regard to our products.

We hereby confirm that the guarantee related to our products also extends to the company **"CAVATEH M SRL".**

This Letter of Authorization is valid until 31.12.2022.

Biotronik AG

DocuSigned by:
Udo Tegtmeyer
CD0EC69766E14BC...

p.p. Udo Tegtmeyer
Vice President CENEMEA

DocuSigned by:
Katrin Mayr-Baxmann
895E1F11AC054F9...

Katrin Mayr-Baxmann
Senior Legal Counsel

BIOTRONIK
BIOTRONIK AG
Ackerstrasse 6
Ch-8180 Bülach

By Royal Charter

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

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. **12-05-01** Issue: 7

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-14 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:	68 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: 16.MAY.2012

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

Signature:

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

A11 REG 151644 EN 04

Scope of DoC No. 12-05-01

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Usable length [cm]
1	Passeo-14 1.5/20/120	380271	1.5	20	120
2	Passeo-14 2/20/120	380272	2.0	20	120
3	Passeo-14 2.5/20/90	380273	2.5	20	90
4	Passeo-14 3/20/90	380274	3.0	20	90
5	Passeo-14 3.5/20/90	380275	3.5	20	90
6	Passeo-14 4/20/90	380276	4.0	20	90
7	Passeo-14 1.5/40/120	380277	1.5	40	120
8	Passeo-14 2/40/120	380278	2.0	40	120
9	Passeo-14 2.5/40/90	380279	2.5	40	90
10	Passeo-14 3/40/90	380280	3.0	40	90
11	Passeo-14 3.5/40/90	380281	3.5	40	90
12	Passeo-14 4/40/90	380282	4.0	40	90
13	Passeo-14 1.5/70/120	380283	1.5	70	120
14	Passeo-14 2/70/120	380284	2.0	70	120
15	Passeo-14 2.5/70/90	380285	2.5	70	90
16	Passeo-14 3/70/90	380286	3.0	70	90
17	Passeo-14 3.5/70/90	380287	3.5	70	90
18	Passeo-14 4/70/90	380288	4.0	70	90
19	Passeo-14 2/100/120	380290	2.0	100	120
20	Passeo-14 2.5/100/90	380291	2.5	100	90
21	Passeo-14 3/100/90	380292	3.0	100	90
22	Passeo-14 3.5/100/90	380293	3.5	100	90
23	Passeo-14 4/100/90	380294	4.0	100	90
24	Passeo-14 2/140/120	380296	2.0	140	120
25	Passeo-14 2.5/140/90	380297	2.5	140	90
26	Passeo-14 3/140/90	380298	3.0	140	90
27	Passeo-14 3.5/140/90	380299	3.5	140	90
28	Passeo-14 4/140/90	380300	4.0	140	90
29	Passeo-14 2/180/120	380302	2.0	180	120
30	Passeo-14 2.5/180/90	380303	2.5	180	90
31	Passeo-14 3/180/90	380304	3.0	180	90
32	Passeo-14 2/220/120	380308	2.0	220	120
33	Passeo-14 2.5/220/90	380309	2.5	220	90
34	Passeo-14 3/220/90	380310	3.0	220	90
35	Passeo-14 1.5/20/150	380313	1.5	20	150
36	Passeo-14 2/20/150	380314	2.0	20	150
37	Passeo-14 2.5/20/150	380315	2.5	20	150
38	Passeo-14 3/20/150	380316	3.0	20	150
39	Passeo-14 3.5/20/150	380317	3.5	20	150
40	Passeo-14 4/20/150	380318	4.0	20	150
41	Passeo-14 1.5/40/150	380319	1.5	40	150
42	Passeo-14 2/40/150	380320	2.0	40	150
43	Passeo-14 2.5/40/150	380321	2.5	40	150
44	Passeo-14 3/40/150	380322	3.0	40	150

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Usable length [cm]
45	Passeo-14 3.5/40/150	380323	3.5	40	150
46	Passeo-14 4/40/150	380324	4.0	40	150
47	Passeo-14 1.5/70/150	380325	1.5	70	150
48	Passeo-14 2/70/150	380326	2.0	70	150
49	Passeo-14 2.5/70/150	380327	2.5	70	150
50	Passeo-14 3/70/150	380328	3.0	70	150
51	Passeo-14 3.5/70/150	380329	3.5	70	150
52	Passeo-14 4/70/150	380330	4.0	70	150
53	Passeo-14 2/100/150	380332	2.0	100	150
54	Passeo-14 2.5/100/150	380333	2.5	100	150
55	Passeo-14 3/100/150	380334	3.0	100	150
56	Passeo-14 3.5/100/150	380335	3.5	100	150
57	Passeo-14 4/100/150	380336	4.0	100	150
58	Passeo-14 2/140/150	380338	2.0	140	150
59	Passeo-14 2.5/140/150	380339	2.5	140	150
60	Passeo-14 3/140/150	380340	3.0	140	150
61	Passeo-14 3.5/140/150	380341	3.5	140	150
62	Passeo-14 4/140/150	380342	4.0	140	150
63	Passeo-14 2/180/150	380344	2.0	180	150
64	Passeo-14 2.5/180/150	380345	2.5	180	150
65	Passeo-14 3/180/150	380346	3.0	180	150
66	Passeo-14 2/220/150	380350	2.0	220	150
67	Passeo-14 2.5/220/150	380351	2.5	220	150
68	Passeo-14 3/220/150	380352	3.0	220	150

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 "Passeo-14_DOC_120501_issue3". New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
02	Corrected to TMP 110093 due to corrected CE 608280 expiry date to 2019-AUG-3, and addition of a new sterilizer (Sterimed).
03	New issue initiated by an update of the EC Full Quality Assurance System Certificate, having a new expiry date.
04	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

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DOC No. 09-05-01 Issue: 19

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-18 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:	144 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: 08.SEP.2006

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

Signature:

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

A11 REG 151647 EN 05

Scope of DoC No. 09-05-01

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Usable length [cm]
1	Passeo-18 2/20/90	366098	2.0	20	90
2	Passeo-18 2.5/20/90	357451	2.5	20	90
3	Passeo-18 3/20/90	357452	3.0	20	90
4	Passeo-18 3.5/20/90	357453	3.5	20	90
5	Passeo-18 4/20/90	357454	4.0	20	90
6	Passeo-18 5/20/90	357455	5.0	20	90
7	Passeo-18 6/20/90	357456	6.0	20	90
8	Passeo-18 7/20/90	357457	7.0	20	90
9	Passeo-18 2/40/90	366099	2.0	40	90
10	Passeo-18 2.5/40/90	357458	2.5	40	90
11	Passeo-18 3/40/90	357459	3.0	40	90
12	Passeo-18 3.5/40/90	357460	3.5	40	90
13	Passeo-18 4/40/90	357461	4.0	40	90
14	Passeo-18 5/40/90	357462	5.0	40	90
15	Passeo-18 6/40/90	357463	6.0	40	90
16	Passeo-18 7/40/90	357464	7.0	40	90
17	Passeo-18 2/60/90	366100	2.0	60	90
18	Passeo-18 2.5/60/90	366101	2.5	60	90
19	Passeo-18 3/60/90	366102	3.0	60	90
20	Passeo-18 3.5/60/90	366103	3.5	60	90
21	Passeo-18 4/60/90	357465	4.0	60	90
22	Passeo-18 5/60/90	357466	5.0	60	90
23	Passeo-18 6/60/90	357467	6.0	60	90
24	Passeo-18 7/60/90	357468	7.0	60	90
25	Passeo-18 2/80/90	366104	2.0	80	90
26	Passeo-18 2.5/80/90	357469	2.5	80	90
27	Passeo-18 3/80/90	357470	3.0	80	90
28	Passeo-18 3.5/80/90	357471	3.5	80	90
29	Passeo-18 4/80/90	357472	4.0	80	90
30	Passeo-18 5/80/90	357473	5.0	80	90
31	Passeo-18 6/80/90	357474	6.0	80	90
32	Passeo-18 7/80/90	357475	7.0	80	90
33	Passeo-18 2/120/90	366105	2.0	120	90
34	Passeo-18 2.5/120/90	357476	2.5	120	90
35	Passeo-18 3/120/90	357477	3.0	120	90
36	Passeo-18 3.5/120/90	357478	3.5	120	90
37	Passeo-18 4/120/90	357479	4.0	120	90
38	Passeo-18 5/120/90	357480	5.0	120	90
39	Passeo-18 6/120/90	357481	6.0	120	90
40	Passeo-18 7/120/90	357482	7.0	120	90
41	Passeo-18 2/150/90	366106	2.0	150	90
42	Passeo-18 2.5/150/90	366107	2.5	150	90
43	Passeo-18 3/150/90	366108	3.0	150	90

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Usable length [cm]
44	Passeo-18 3.5/150/90	366109	3.5	150	90
45	Passeo-18 4/150/90	366110	4.0	150	90
46	Passeo-18 5/150/90	366111	5.0	150	90
47	Passeo-18 6/150/90	366112	6.0	150	90
48	Passeo-18 7/150/90	366113	7.0	150	90
49	Passeo-18 2/170/90	366114	2.0	170	90
50	Passeo-18 2.5/170/90	357483	2.5	170	90
51	Passeo-18 3/170/90	357484	3.0	170	90
52	Passeo-18 3.5/170/90	357485	3.5	170	90
53	Passeo-18 4/170/90	376272	4.0	170	90
54	Passeo-18 5/170/90	376273	5.0	170	90
55	Passeo-18 6/170/90	376274	6.0	170	90
56	Passeo-18 7/170/90	376275	7.0	170	90
57	Passeo-18 2/200/90	376276	2.0	200	90
58	Passeo-18 2.5/200/90	376277	2.5	200	90
59	Passeo-18 3/200/90	376278	3.0	200	90
60	Passeo-18 3.5/200/90	376279	3.5	200	90
61	Passeo-18 4/200/90	376280	4.0	200	90
62	Passeo-18 5/200/90	376281	5.0	200	90
63	Passeo-18 6/200/90	376282	6.0	200	90
64	Passeo-18 7/200/90	376283	7.0	200	90
65	Passeo-18 2/220/90	376284	2.0	220	90
66	Passeo-18 2.5/220/90	376285	2.5	220	90
67	Passeo-18 3/220/90	376286	3.0	220	90
68	Passeo-18 3.5/220/90	376287	3.5	220	90
69	Passeo-18 4/220/90	376288	4.0	220	90
70	Passeo-18 5/220/90	376289	5.0	220	90
71	Passeo-18 6/220/90	376290	6.0	220	90
72	Passeo-18 7/220/90	376291	7.0	220	90
73	Passeo-18 2.5/20/130	357486	2.5	20	130
74	Passeo-18 3/20/130	357487	3.0	20	130
75	Passeo-18 3.5/20/130	357488	3.5	20	130
76	Passeo-18 4/20/130	357489	4.0	20	130
77	Passeo-18 5/20/130	357490	5.0	20	130
78	Passeo-18 6/20/130	366116	6.0	20	130
79	Passeo-18 7/20/130	366117	7.0	20	130
80	Passeo-18 2.5/40/130	357491	2.5	40	130
81	Passeo-18 3/40/130	357492	3.0	40	130
82	Passeo-18 3.5/40/130	357493	3.5	40	130
83	Passeo-18 4/40/130	357494	4.0	40	130
84	Passeo-18 5/40/130	357495	5.0	40	130
85	Passeo-18 6/40/130	357496	6.0	40	130
86	Passeo-18 7/40/130	357497	7.0	40	130
87	Passeo-18 2.5/60/130	366120	2.5	60	130
88	Passeo-18 3/60/130	366121	3.0	60	130

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Usable length [cm]
89	Passeo-18 3.5/60/130	366122	3.5	60	130
90	Passeo-18 4/60/130	357498	4.0	60	130
91	Passeo-18 5/60/130	357499	5.0	60	130
92	Passeo-18 6/60/130	357500	6.0	60	130
93	Passeo-18 7/60/130	357501	7.0	60	130
94	Passeo-18 2.5/80/130	357502	2.5	80	130
95	Passeo-18 3.0/80/130	357503	3.0	80	130
96	Passeo-18 3.5/80/130	357504	3.5	80	130
97	Passeo-18 4/80/130	357505	4.0	80	130
98	Passeo-18 5/80/130	357506	5.0	80	130
99	Passeo-18 6/80/130	366124	6.0	80	130
100	Passeo-18 7/80/130	366125	7.0	80	130
101	Passeo-18 2.5/120/130	357507	2.5	120	130
102	Passeo-18 3/120/130	357508	3.0	120	130
103	Passeo-18 3.5/120/130	357509	3.5	120	130
104	Passeo-18 4/120/130	357510	4.0	120	130
105	Passeo-18 5/120/130	357511	5.0	120	130
106	Passeo-18 6/120/130	366127	6.0	120	130
107	Passeo-18 7/120/130	366128	7.0	120	130
108	Passeo-18 2.5/150/130	366130	2.5	150	130
109	Passeo-18 3/150/130	366131	3.0	150	130
110	Passeo-18 3.5/150/130	366132	3.5	150	130
111	Passeo-18 4/150/130	366133	4.0	150	130
112	Passeo-18 5/150/130	366134	5.0	150	130
113	Passeo-18 6/150/130	366135	6.0	150	130
114	Passeo-18 7/150/130	366136	7.0	150	130
115	Passeo-18 2.5/170/130	357512	2.5	170	130
116	Passeo-18 3/170/130	357513	3.0	170	130
117	Passeo-18 3.5/170/130	357514	3.5	170	130
118	Passeo-18 4/170/130	376292	4.0	170	130
119	Passeo-18 5/170/130	376293	5.0	170	130
120	Passeo-18 6/170/130	376294	6.0	170	130
121	Passeo-18 7/170/130	376295	7.0	170	130
122	Passeo-18 2.5/200/130	376297	2.5	200	130
123	Passeo-18 3/200/130	376298	3.0	200	130
124	Passeo-18 3.5/200/130	376299	3.5	200	130
125	Passeo-18 4/200/130	376300	4.0	200	130
126	Passeo-18 5/200/130	376301	5.0	200	130
127	Passeo-18 6/200/130	376302	6.0	200	130
128	Passeo-18 7/200/130	376303	7.0	200	130
129	Passeo-18 2.5/220/130	376305	2.5	220	130
130	Passeo-18 3/220/130	376306	3.0	220	130
131	Passeo-18 3.5/220/130	376307	3.5	220	130
132	Passeo-18 4/220/130	376308	4.0	220	130

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Usable length [cm]
133	Passeo-18 5/220/130	376309	5.0	220	130
134	Passeo-18 6/220/130	376310	6.0	220	130
135	Passeo-18 7/220/130	376311	7.0	220	130
136	Passeo-18 2/20/150	366115	2.0	20	150
137	Passeo-18 2/40/150	366118	2.0	40	150
138	Passeo-18 2/60/150	366119	2.0	60	150
139	Passeo-18 2/80/150	366123	2.0	80	150
140	Passeo-18 2/120/150	366126	2.0	120	150
141	Passeo-18 2/150/150	366129	2.0	150	150
142	Passeo-18 2/170/150	366137	2.0	170	150
143	Passeo-18 2/200/150	376296	2.0	200	150
144	Passeo-18 2/220/150	376304	2.0	220	150

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 "Passeo-18_DOC_060901_issue14". New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
02	Corrected to TMP 110093, corrected CE 608280 expiry date to 2019-AUG-31 and addition of sterilizer (Sterimed).
03	New issue initiated by an update of the EC Full Quality Assurance System Certificate, having a new expiry date
04	Addition of Passeo-18 7/40/130 with mat. Nr. 357497: This size is initially validated and part of the product scope but was mistakenly deleted from the table (Pos. 86 was missing in ver. 03).
05	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

BIOTRONIK
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DOC No. 19-09-01 Issue: 02

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 Xeo 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:	219 different variants. See list of products on 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: 30.SEP.2019

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

Signature:

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

A11 REG 155052 EN 02

Scope of DoC No. 19-09-01

Table 1: Table of product range including 219 product size

#	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
1	Passeo-35 Xeo 3/20/90	428777	3	20	90
2	Passeo-35 Xeo 4/20/90	428778	4	20	90
3	Passeo-35 Xeo 5/20/90	428779	5	20	90
4	Passeo-35 Xeo 6/20/90	428780	6	20	90
5	Passeo-35 Xeo 7/20/90	428781	7	20	90
6	Passeo-35 Xeo 8/20/90	428782	8	20	90
7	Passeo-35 Xeo 9/20/90	428783	9	20	90
8	Passeo-35 Xeo 10/20/90	428784	10	20	90
9	Passeo-35 Xeo 3/40/90	428786	3	40	90
10	Passeo-35 Xeo 4/40/90	428787	4	40	90
11	Passeo-35 Xeo 5/40/90	428788	5	40	90
12	Passeo-35 Xeo 6/40/90	428789	6	40	90
13	Passeo-35 Xeo 7/40/90	428790	7	40	90
14	Passeo-35 Xeo 8/40/90	428791	8	40	90
15	Passeo-35 Xeo 9/40/90	428792	9	40	90
16	Passeo-35 Xeo 10/40/90	428793	10	40	90
17	Passeo-35 Xeo 12/40/90	428794	12	40	90
18	Passeo-35 Xeo 3/60/90	428795	3	60	90
19	Passeo-35 Xeo 4/60/90	428796	4	60	90
20	Passeo-35 Xeo 5/60/90	428797	5	60	90
21	Passeo-35 Xeo 6/60/90	428798	6	60	90
22	Passeo-35 Xeo 7/60/90	428799	7	60	90
23	Passeo-35 Xeo 8/60/90	428800	8	60	90
24	Passeo-35 Xeo 9/60/90	428801	9	60	90
25	Passeo-35 Xeo 10/60/90	428802	10	60	90

#	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
26	Passeo-35 Xeo 12/60/90	428803	12	60	90
27	Passeo-35 Xeo 3/80/90	428804	3	80	90
28	Passeo-35 Xeo 4/80/90	428805	4	80	90
29	Passeo-35 Xeo 5/80/90	428806	5	80	90
30	Passeo-35 Xeo 6/80/90	428807	6	80	90
31	Passeo-35 Xeo 7/80/90	428808	7	80	90
32	Passeo-35 Xeo 8/80/90	428809	8	80	90
33	Passeo-35 Xeo 9/80/90	428810	9	80	90
34	Passeo-35 Xeo 10/80/90	428811	10	80	90
35	Passeo-35 Xeo 12/80/90	428812	12	80	90
36	Passeo-35 Xeo 3/100/90	428813	3	100	90
37	Passeo-35 Xeo 4/100/90	428814	4	100	90
38	Passeo-35 Xeo 5/100/90	428815	5	100	90
39	Passeo-35 Xeo 6/100/90	428816	6	100	90
40	Passeo-35 Xeo 7/100/90	428817	7	100	90
41	Passeo-35 Xeo 8/100/90	428818	8	100	90
42	Passeo-35 Xeo 9/100/90	428819	9	100	90
43	Passeo-35 Xeo 10/100/90	428820	10	100	90
44	Passeo-35 Xeo 12/100/90	428821	12	100	90
45	Passeo-35 Xeo 3/120/90	428822	3	120	90
46	Passeo-35 Xeo 4/120/90	428823	4	120	90
47	Passeo-35 Xeo 5/120/90	428824	5	120	90
48	Passeo-35 Xeo 6/120/90	428825	6	120	90
49	Passeo-35 Xeo 7/120/90	428826	7	120	90
50	Passeo-35 Xeo 8/120/90	428827	8	120	90
51	Passeo-35 Xeo 9/120/90	428828	9	120	90
52	Passeo-35 Xeo 10/120/90	428829	10	120	90
53	Passeo-35 Xeo 12/120/90	428830	12	120	90

#	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
54	Passeo-35 Xeo 3/150/90	428831	3	150	90
55	Passeo-35 Xeo 4/150/90	428832	4	150	90
56	Passeo-35 Xeo 5/150/90	428833	5	150	90
57	Passeo-35 Xeo 6/150/90	428834	6	150	90
58	Passeo-35 Xeo 7/150/90	428835	7	150	90
59	Passeo-35 Xeo 3/170/90	428836	3	170	90
60	Passeo-35 Xeo 4/170/90	428837	4	170	90
61	Passeo-35 Xeo 5/170/90	428838	5	170	90
62	Passeo-35 Xeo 6/170/90	428839	6	170	90
63	Passeo-35 Xeo 7/170/90	428840	7	170	90
64	Passeo-35 Xeo 3/200/90	428841	3	200	90
65	Passeo-35 Xeo 4/200/90	428842	4	200	90
66	Passeo-35 Xeo 5/200/90	428843	5	200	90
67	Passeo-35 Xeo 6/200/90	428844	6	200	90
68	Passeo-35 Xeo 7/200/90	428845	7	200	90
69	Passeo-35 Xeo 3/250/90	428846	3	250	90
70	Passeo-35 Xeo 4/250/90	428847	4	250	90
71	Passeo-35 Xeo 5/250/90	428848	5	250	90
72	Passeo-35 Xeo 6/250/90	428849	6	250	90
73	Passeo-35 Xeo 7/250/90	428850	7	250	90
74	Passeo-35 Xeo 3/20/130	428851	3	20	130
75	Passeo-35 Xeo 4/20/130	428852	4	20	130
76	Passeo-35 Xeo 5/20/130	428853	5	20	130
77	Passeo-35 Xeo 6/20/130	428854	6	20	130
78	Passeo-35 Xeo 7/20/130	428855	7	20	130
79	Passeo-35 Xeo 8/20/130	428856	8	20	130
80	Passeo-35 Xeo 9/20/130	428857	9	20	130
81	Passeo-35 Xeo 10/20/130	428858	10	20	130

#	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
82	Passeo-35 Xeo 3/40/130	428860	3	40	130
83	Passeo-35 Xeo 4/40/130	428861	4	40	130
84	Passeo-35 Xeo 5/40/130	428862	5	40	130
85	Passeo-35 Xeo 6/40/130	428863	6	40	130
86	Passeo-35 Xeo 7/40/130	428864	7	40	130
87	Passeo-35 Xeo 8/40/130	428865	8	40	130
88	Passeo-35 Xeo 9/40/130	428866	9	40	130
89	Passeo-35 Xeo 10/40/130	428867	10	40	130
90	Passeo-35 Xeo 12/40/130	428868	12	40	130
91	Passeo-35 Xeo 3/60/130	428869	3	60	130
92	Passeo-35 Xeo 4/60/130	428870	4	60	130
93	Passeo-35 Xeo 5/60/130	428871	5	60	130
94	Passeo-35 Xeo 6/60/130	428872	6	60	130
95	Passeo-35 Xeo 7/60/130	428873	7	60	130
96	Passeo-35 Xeo 8/60/130	428874	8	60	130
97	Passeo-35 Xeo 9/60/130	428875	9	60	130
98	Passeo-35 Xeo 10/60/130	428876	10	60	130
99	Passeo-35 Xeo 12/60/130	428877	12	60	130
100	Passeo-35 Xeo 3/80/130	428878	3	80	130
101	Passeo-35 Xeo 4/80/130	428879	4	80	130
102	Passeo-35 Xeo 5/80/130	428880	5	80	130
103	Passeo-35 Xeo 6/80/130	428881	6	80	130
104	Passeo-35 Xeo 7/80/130	428882	7	80	130
105	Passeo-35 Xeo 8/80/130	428883	8	80	130
106	Passeo-35 Xeo 9/80/130	428884	9	80	130
107	Passeo-35 Xeo 10/80/130	428885	10	80	130
108	Passeo-35 Xeo 12/80/130	428886	12	80	130
109	Passeo-35 Xeo 3/100/130	428887	3	100	130

#	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
110	Passeo-35 Xeo 4/100/130	428888	4	100	130
111	Passeo-35 Xeo 5/100/130	428889	5	100	130
112	Passeo-35 Xeo 6/100/130	428890	6	100	130
113	Passeo-35 Xeo 7/100/130	428891	7	100	130
114	Passeo-35 Xeo 8/100/130	428892	8	100	130
115	Passeo-35 Xeo 9/100/130	428893	9	100	130
116	Passeo-35 Xeo 10/100/130	428894	10	100	130
117	Passeo-35 Xeo 12/100/130	428895	12	100	130
118	Passeo-35 Xeo 3/120/130	428896	3	120	130
119	Passeo-35 Xeo 4/120/130	428897	4	120	130
120	Passeo-35 Xeo 5/120/130	428898	5	120	130
121	Passeo-35 Xeo 6/120/130	428899	6	120	130
122	Passeo-35 Xeo 7/120/130	428900	7	120	130
123	Passeo-35 Xeo 8/120/130	428901	8	120	130
124	Passeo-35 Xeo 9/120/130	428902	9	120	130
125	Passeo-35 Xeo 10/120/130	428903	10	120	130
126	Passeo-35 Xeo 12/120/130	428904	12	120	130
127	Passeo-35 Xeo 3/150/130	428905	3	150	130
128	Passeo-35 Xeo 4/150/130	428906	4	150	130
129	Passeo-35 Xeo 5/150/130	428907	5	150	130
130	Passeo-35 Xeo 6/150/130	428908	6	150	130
131	Passeo-35 Xeo 7/150/130	428909	7	150	130
132	Passeo-35 Xeo 3/170/130	428910	3	170	130
133	Passeo-35 Xeo 4/170/130	428911	4	170	130
134	Passeo-35 Xeo 5/170/130	428912	5	170	130
135	Passeo-35 Xeo 6/170/130	428913	6	170	130
136	Passeo-35 Xeo 7/170/130	428914	7	170	130
137	Passeo-35 Xeo 3/200/130	428915	3	200	130

#	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
138	Passeo-35 Xeo 4/200/130	428916	4	200	130
139	Passeo-35 Xeo 5/200/130	428917	5	200	130
140	Passeo-35 Xeo 6/200/130	428918	6	200	130
141	Passeo-35 Xeo 7/200/130	428919	7	200	130
142	Passeo-35 Xeo 3/250/130	428920	3	250	130
143	Passeo-35 Xeo 4/250/130	428921	4	250	130
144	Passeo-35 Xeo 5/250/130	428922	5	250	130
145	Passeo-35 Xeo 6/250/130	428923	6	250	130
146	Passeo-35 Xeo 7/250/130	428924	7	250	130
147	Passeo-35 Xeo 3/20/170	428925	3	20	170
148	Passeo-35 Xeo 4/20/170	428926	4	20	170
149	Passeo-35 Xeo 5/20/170	428927	5	20	170
150	Passeo-35 Xeo 6/20/170	428928	6	20	170
151	Passeo-35 Xeo 7/20/170	428929	7	20	170
152	Passeo-35 Xeo 8/20/170	428930	8	20	170
153	Passeo-35 Xeo 9/20/170	428931	9	20	170
154	Passeo-35 Xeo 10/20/170	428932	10	20	170
155	Passeo-35 Xeo 3/40/170	428934	3	40	170
156	Passeo-35 Xeo 4/40/170	428935	4	40	170
157	Passeo-35 Xeo 5/40/170	428936	5	40	170
158	Passeo-35 Xeo 6/40/170	428937	6	40	170
159	Passeo-35 Xeo 7/40/170	428938	7	40	170
160	Passeo-35 Xeo 8/40/170	428939	8	40	170
161	Passeo-35 Xeo 9/40/170	428940	9	40	170
162	Passeo-35 Xeo 10/40/170	428941	10	40	170
163	Passeo-35 Xeo 12/40/170	428942	12	40	170
164	Passeo-35 Xeo 3/60/170	428943	3	60	170
165	Passeo-35 Xeo 4/60/170	428944	4	60	170

#	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
166	Passeo-35 Xeo 5/60/170	428945	5	60	170
167	Passeo-35 Xeo 6/60/170	428946	6	60	170
168	Passeo-35 Xeo 7/60/170	428947	7	60	170
169	Passeo-35 Xeo 8/60/170	428948	8	60	170
170	Passeo-35 Xeo 9/60/170	428949	9	60	170
171	Passeo-35 Xeo 10/60/170	428950	10	60	170
172	Passeo-35 Xeo 12/60/170	428951	12	60	170
173	Passeo-35 Xeo 3/80/170	428952	3	80	170
174	Passeo-35 Xeo 4/80/170	428953	4	80	170
175	Passeo-35 Xeo 5/80/170	428954	5	80	170
176	Passeo-35 Xeo 6/80/170	428955	6	80	170
177	Passeo-35 Xeo 7/80/170	428956	7	80	170
178	Passeo-35 Xeo 8/80/170	428957	8	80	170
179	Passeo-35 Xeo 9/80/170	428958	9	80	170
180	Passeo-35 Xeo 10/80/170	428959	10	80	170
181	Passeo-35 Xeo 12/80/170	428960	12	80	170
182	Passeo-35 Xeo 3/100/170	428961	3	100	170
183	Passeo-35 Xeo 4/100/170	428962	4	100	170
184	Passeo-35 Xeo 5/100/170	428963	5	100	170
185	Passeo-35 Xeo 6/100/170	428964	6	100	170
186	Passeo-35 Xeo 7/100/170	428965	7	100	170
187	Passeo-35 Xeo 8/100/170	428966	8	100	170
188	Passeo-35 Xeo 9/100/170	428967	9	100	170
189	Passeo-35 Xeo 10/100/170	428968	10	100	170
190	Passeo-35 Xeo 12/100/170	428969	12	100	170
191	Passeo-35 Xeo 3/120/170	428970	3	120	170
192	Passeo-35 Xeo 4/120/170	428971	4	120	170
193	Passeo-35 Xeo 5/120/170	428972	5	120	170

#	Designation	Catalogue number (REF)	Nominal Balloon Ø [mm]	Nominal Balloon length [mm]	Usable length [cm]
194	Passeo-35 Xeo 6/120/170	428973	6	120	170
195	Passeo-35 Xeo 7/120/170	428974	7	120	170
196	Passeo-35 Xeo 8/120/170	428975	8	120	170
197	Passeo-35 Xeo 9/120/170	428976	9	120	170
198	Passeo-35 Xeo 10/120/170	428977	10	120	170
199	Passeo-35 Xeo 12/120/170	428978	12	120	170
200	Passeo-35 Xeo 3/150/170	428979	3	150	170
201	Passeo-35 Xeo 4/150/170	428980	4	150	170
202	Passeo-35 Xeo 5/150/170	428981	5	150	170
203	Passeo-35 Xeo 6/150/170	428982	6	150	170
204	Passeo-35 Xeo 7/150/170	428983	7	150	170
205	Passeo-35 Xeo 3/170/170	428984	3	170	170
206	Passeo-35 Xeo 4/170/170	428985	4	170	170
207	Passeo-35 Xeo 5/170/170	428986	5	170	170
208	Passeo-35 Xeo 6/170/170	428987	6	170	170
209	Passeo-35 Xeo 7/170/170	428988	7	170	170
210	Passeo-35 Xeo 3/200/170	428989	3	200	170
211	Passeo-35 Xeo 4/200/170	428990	4	200	170
212	Passeo-35 Xeo 5/200/170	428991	5	200	170
213	Passeo-35 Xeo 6/200/170	428992	6	200	170
214	Passeo-35 Xeo 7/200/170	428993	7	200	170
215	Passeo-35 Xeo 3/250/170	428994	3	250	170
216	Passeo-35 Xeo 4/250/170	428995	4	250	170
217	Passeo-35 Xeo 5/250/170	428996	5	250	170
218	Passeo-35 Xeo 6/250/170	428997	6	250	170
219	Passeo-35 Xeo 7/250/170	428998	7	250	170

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 - Initial release for a new product
02	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

BIOTRONIK
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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. 12-03-01 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:	Pulsar-35 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:	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.

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: 01.MAR.2012

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

Signature:

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

A11 REG 151635 EN 03

Scope of DoC No. 12-03-01

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Usable length [cm]
1	Pulsar-35 5/30/90	379878	5	30	90
2	Pulsar-35 5/40/90	379879	5	40	90
3	Pulsar-35 5/60/90	379880	5	60	90
4	Pulsar-35 5/80/90	379881	5	80	90
5	Pulsar-35 6/30/90	379883	6	30	90
6	Pulsar-35 6/40/90	379884	6	40	90
7	Pulsar-35 6/60/90	379885	6	60	90
8	Pulsar-35 6/80/90	379886	6	80	90
9	Pulsar-35 7/30/90	379888	7	30	90
10	Pulsar-35 7/40/90	379889	7	40	90
11	Pulsar-35 7/60/90	379890	7	60	90
12	Pulsar-35 7/80/90	379891	7	80	90
13	Pulsar-35 5/30/135	379898	5	30	135
14	Pulsar-35 5/40/135	379899	5	40	135
15	Pulsar-35 5/60/135	379900	5	60	135
16	Pulsar-35 5/80/135	379901	5	80	135
17	Pulsar-35 6/30/135	379903	6	30	135
18	Pulsar-35 6/40/135	379904	6	40	135
19	Pulsar-35 6/60/135	379905	6	60	135
20	Pulsar-35 6/80/135	379906	6	80	135
21	Pulsar-35 7/30/135	379908	7	30	135
22	Pulsar-35 7/40/135	379909	7	40	135
23	Pulsar-35 7/60/135	379910	7	60	135
24	Pulsar-35 7/80/135	379911	7	80	135
25	Pulsar-35 5/100/90	379917	5	100	90
26	Pulsar-35 5/120/90	379918	5	120	90
27	Pulsar-35 5/150/90	379919	5	150	90
28	Pulsar-35 5/170/90	379920	5	170	90
29	Pulsar-35 5/200/90	379921	5	200	90
30	Pulsar-35 6/100/90	379922	6	100	90
31	Pulsar-35 6/120/90	379923	6	120	90
32	Pulsar-35 6/150/90	379924	6	150	90
33	Pulsar-35 6/170/90	379925	6	170	90
34	Pulsar-35 6/200/90	379926	6	200	90
35	Pulsar-35 7/100/90	379927	7	100	90
36	Pulsar-35 7/120/90	379928	7	120	90
37	Pulsar-35 7/150/90	379929	7	150	90
38	Pulsar-35 7/170/90	379930	7	170	90
39	Pulsar-35 7/200/90	379931	7	200	90
40	Pulsar-35 5/100/135	379937	5	100	135
41	Pulsar-35 5/120/135	379938	5	120	135
42	Pulsar-35 5/150/135	379939	5	150	135
43	Pulsar-35 5/170/135	379940	5	170	135

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Usable length [cm]
44	Pulsar-35 5/200/135	379941	5	200	135
45	Pulsar-35 6/100/135	379942	6	100	135
46	Pulsar-35 6/120/135	379943	6	120	135
47	Pulsar-35 6/150/135	379944	6	150	135
48	Pulsar-35 6/170/135	379945	6	170	135
49	Pulsar-35 6/200/135	379946	6	200	135
50	Pulsar-35 7/100/135	379947	7	100	135
51	Pulsar-35 7/120/135	379948	7	120	135
52	Pulsar-35 7/150/135	379949	7	150	135
53	Pulsar-35 7/170/135	379950	7	170	135
54	Pulsar-35 7/200/135	379951	7	200	135

Change History

Version of SAP Document	Main changes from previous release to current release
01	New Document using current template. Replaces "Pulsar-35 DOC 120301 Issue2". 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. Product name aligned to labelling and STED.
03	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

BIOTRONIK
excellence for life

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.

EC-Declaration of Conformity

BIOTRONIK
excellence for life

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.

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
FF33BDA9BAA9EA3...
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 Aspiration catheter ECD 12 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
Technical File:	TDR04030102
EC Product Class:	Class III according to Annex IX, Rule 6 of the Directive
Applicable certificate:	Certificate n° 23251 rev. 9
Product range:	cf table here enclosed
Notified body:	GMED 1, rue Gaston Boissier 75015 PARIS France

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 GMED (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: 14/12/2020

Signature:

3 FLOW catheter

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

The references are:

Table 1 : 3 Flow part numbers

Product code	Designation
04030241	3Flow 6F sterile
04030242	3Flow 7F sterile

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 9775 rev. 6

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ARTHESYS

4 rue René Razel

91400 SACLAY FRANCE

pour les activités

for the activities

Conception, fabrication et commercialisation de dispositifs médicaux pour le traitement thérapeutique du système vasculaire.
Sous-traitance pour le Transfert de la conception et de Développement et la Fabrication de Connecteurs et de Cathéters pour la Dilatation et l'Aspiration.

Design, manufacture and marketing of medical devices for the therapeutic treatment of the vascular system.
Subcontracting for the Design and Development Transfer and Manufacture of connectors and catheters for dilatation and aspiration.

réalisées sur le(s) site(s) de

performed on the location(s) of

ARTHESYS
4 rue René Razel 91400 SACLAY FRA

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

ISO 13485 : 2016

Début de validité */ Effective date :* **July 20th, 2021 (included)**
Valable jusqu'au */ Expiry date :* **June 9th, 2024 (included)**
Etabli le */ Issued on :* **July 20th, 2021**

DocuSigned by:
Béatrice LYS
EF33BDA9BA...

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

GMED N° 9775–6
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 9775-5

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.