

EC-DECLARATION OF CONFORMITY

DOC No. 07-04-01 Issue: 8

Manufacturer: **Biotronik AG**
Ackerstrasse 6
8180 Bülach
Switzerland

Product Category: **PTA balloon catheter**

Product Name: **Passeo-35 Peripheral Dilatation Catheter**

Class: **Ila, 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 at 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, United Kingdom
EEC No:	0086
Date of issue:	01.04.2014

Date of first CE-marking: **02.04.2007**

Place, Date of issue: **Bülach, 01.04.2014**

Signature:



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

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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

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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

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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