

EC-DECLARATION OF CONFORMITY

DOC No. 09-09-01 Issue: 8

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

Product Category: **Drug-releasing PTCA balloon catheter**

Product Name: **Pantera Lux Paclitaxel releasing PTCA Balloon Catheter**

Class: **III, according to Council Directive 93/42/EEC, Annex IX, rule 6 and 13**

Conformity Assessment Route: **Council Directive 93/42/EEC, Annex II, Section 3 and 4**

Scope: **25 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:	608285
Notified Body:	BSI, United Kingdom
EEC No:	0086
Expiry date:	15.09.2021

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:	608280
Notified Body:	BSI, United Kingdom
EEC No:	0086
Expiry date:	31.08.2019

Date of first CE-marking: 22.09.2009

Place, Date of issue: Bülach, 18.08.2016

Signature: 
Marcel Schäfer, Ph.D.
Director Regulatory Affairs

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Scope of DoC No. 09-09-01

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Nominal drug amount [µg]
1	Pantera Lux 2.0/10	365110	2.0	10	227
2	Pantera Lux 2.5/10	365120	2.5	10	321
3	Pantera Lux 3.0/10	365125	3.0	10	415
4	Pantera Lux 3.5/10	365130	3.5	10	510
5	Pantera Lux 4.0/10	365135	4.0	10	604
6	Pantera Lux 2.0/15	365111	2.0	15	288
7	Pantera Lux 2.5/15	365121	2.5	15	405
8	Pantera Lux 3.0/15	365126	3.0	15	523
9	Pantera Lux 3.5/15	365131	3.5	15	641
10	Pantera Lux 4.0/15	365136	4.0	15	759
11	Pantera Lux 2.0/20	365112	2.0	20	351
12	Pantera Lux 2.5/20	365122	2.5	20	492
13	Pantera Lux 3.0/20	365127	3.0	20	634
14	Pantera Lux 3.5/20	365132	3.5	20	775
15	Pantera Lux 4.0/20	365137	4.0	20	916
16	Pantera Lux 2.0/25	365113	2.0	25	415
17	Pantera Lux 2.5/25	365123	2.5	25	580
18	Pantera Lux 3.0/25	365128	3.0	25	745
19	Pantera Lux 3.5/25	365133	3.5	25	910
20	Pantera Lux 4.0/25	365138	4.0	25	1075
21	Pantera Lux 2.0/30	365114	2.0	30	482
22	Pantera Lux 2.5/30	365124	2.5	30	671
23	Pantera Lux 3.0/30	365129	3.0	30	859
24	Pantera Lux 3.5/30	365134	3.5	30	1048
25	Pantera Lux 4.0/30	365139	4.0	30	1236