

EC-DECLARATION OF CONFORMITY

DOC No. 11-02-01 Issue: 11

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

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, United Kingdom
EEC No:	0086
Expiry date:	22.02.2021

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

Date of first CE-marking: 25.02.2011

Place, Date of issue: Bülach, 16 Nov 2016

Signature: 

Marcel Schäfer, Ph.D.
Director Regulatory Affairs

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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

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Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Nominal Total Drug Load TDL [μ g]
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