

# EC-Declaration of Conformity

**DOC No.** 13-06-02      **Issue:** 7  
**Manufacturer:** Biotronik AG  
Ackerstrasse 6  
8180 Bülach  
Switzerland  
**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:

<b>Certificate Number:</b>	CE 608286
<b>Notified Body:</b>	BSI, United Kingdom
<b>EEC No:</b>	0086
<b>Expiry date:</b>	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:

<b>Certificate Number:</b>	CE 608280
<b>Notified Body:</b>	BSI, United Kingdom
<b>EEC No:</b>	0086
<b>Expiry date:</b>	31.Aug.2019

**Date of first CE-marking:** 12.Jun.2013  
**Place, Date of issue:** Bülach, 05.Jun.2018

**Signature:** 

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

## 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.