

# EC-DECLARATION OF CONFORMITY

DOC No. 06-05-01 Issue: 8

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

Product Category: **Coronary and peripheral artery guidewire**

Product Name: **Cruiser and Cruiser Hydro**

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

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

Scope: **15 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:

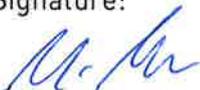
Certificate Number:	<b>CE 619676</b>
Notified Body:	<b>BSI, United Kingdom</b>
EEC No:	<b>0086</b>
Expiry date:	<b>29.09.2019</b>

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:	<b>CE 608280</b>
Notified Body:	<b>BSI, United Kingdom</b>
EEC No:	<b>0086</b>
Expiry date:	<b>31.08.2019</b>

Date of first CE-marking: 24.05.2006

Place, Date of issue: Bülach, 24.03.2016

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

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Scope of DoC No. 06-05-01

Pos.	Designation	Catalogue number (REF)	Shaft Type	Tip flexibility	Tip configuration
1	Cruiser HF	351460	Standard	HF	Straight
2	Cruiser F	351461	Standard	F	Straight
3	Cruiser M	351462	Standard	M	Straight
4	Cruiser HF-J	351463	Standard	HF	J
5	Cruiser F-J	351464	Standard	F	J
6	Cruiser M-J	351465	Standard	M	J
7	Cruiser ES-HF	351466	Extra Support (ES)	HF	Straight
8	Cruiser ES-F	351467	Extra Support (ES)	F	Straight
9	Cruiser ES-HF-J	351468	Extra Support (ES)	HF	J
10	Cruiser ES-F-J	351469	Extra Support (ES)	F	J
11	Cruiser Hydro HF	351455	Standard	HF	Straight
12	Cruiser Hydro F	351456	Standard	F	Straight
13	Cruiser Hydro M	351457	Standard	M	Straight
14	Cruiser Hydro ES-HF	351458	Extra Support (ES)	HF	Straight
15	Cruiser Hydro ES-F	351459	Extra Support (ES)	F	Straight