

MANUFACTURER'S DECLARATION OF CONFORMITY

According to the EC – Medical Devices Directive 93/42/EEC
FULL QUALITY ASSURANCE PROCEDURE

Reference: Trace No. 10-015
Manufacturer's Name: Abbott Laboratories Vascular Enterprises Ltd. Dublin, Beringen Branch
Business Address: Anthoptstrasse, CH-8222 Beringen, Switzerland
Medical Device(s): FoxCross, PTA Catheter
Classification: Class IIa Classification acc. Annex IX MDD 93/42/EEG Rules 6
GMDN Code and Term: 17184 Catheter, angioplasty, balloon dilatation
UMDNS Code and Term: 17-184 Catheter, angioplasty, balloon dilatation

Scope of Application: see attached list

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Management System Certificate:

Assessment Body: TÜV SÜD Product Service GmbH, ID-number: 0123, D-80339 Munich, Germany

Certificate Number: G1 09 12 50497 015 acc. European Medical Devices Directive 93/42/EEC, Annex II, Clause 3

Design Examination Certificate:

Not applicable.

This Declaration is valid as of: March 21st, 2010

Authorized Signatory:


Rainer Schmidt, Sr. Manager Regulatory Affairs

24 March 2010
Date


Kai Göring, Manager Quality Assurance

24 March 2010
Date



Attachment to Declaration of Conformity FoxCross PTA Catheter, ID No. 10-015

Usable length 50 cm

Balloon diameter	Balloon length						
	20	30	40	60	80	100	120
3	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-
5	10300-20	-	10300-40	-	-	-	-
6	10301-20	-	10301-40	-	-	-	-
7	10302-20	-	10302-40	-	-	-	-
8	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-

Usable length 80 cm

Balloon diameter	Balloon length						
	20	30	40	60	80	100	120
3	10303-20	-	10303-40	-	10303-80	-	-
4	10304-20	-	10304-40	10304-60	10304-80	10304-100	10304-120
5	10305-20	10305-30	10305-40	10305-60	10305-80	10305-100	10305-120
6	10306-20	10306-30	10306-40	10306-60	10306-80	10306-100	10306-120
7	10307-20	10307-30	10307-40	10307-60	10307-80	10307-100	10307-120
8	10308-20	10308-30	10308-40	10308-60	10308-80	-	-
9	10309-20	10309-30	10309-40	10309-60	-	-	-
10	10310-20	10310-30	10310-40	10310-60	-	-	-
12	10311-20	10311-30	10311-40	10311-60	-	-	-
14	10344-20	-	10344-40	-	-	-	-


Usable length 135 cm

Balloon diameter	Balloon length						
	20	30	40	60	80	100	120
3	10312-20	-	10312-40	-	10312-80	-	-
4	10313-20	-	10313-40	10313-60	10313-80	10313-100	10313-120
5	10314-20	10314-30	10314-40	10314-60	10314-80	10314-100	10314-120
6	10315-20	10315-30	10315-40	10315-60	10315-80	10315-100	10315-120
7	10316-20	10316-30	10316-40	10316-60	-	10316-100	10316-120
8	10317-20	10317-30	10317-40	-	-	-	-
9	10318-20	10318-30	10318-40	-	-	-	-
10	10319-20	10319-30	10319-40	-	-	-	-
12	10320-20	-	10320-40	-	-	-	-
14	10345-20	-	10345-40	-	-	-	-

Authorized Signatory:


 Rainer Schmidt, Sr Manager Regulatory Affairs

24 March 2010
 Date


 Kai Görling, Manager Quality Assurance

24 March 2010
 Date