

MANUFACTURER'S DECLARATION OF CONFORMITY

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

Reference: Trace No. 10-011
Manufacturer's Name: Abbott Laboratories Vascular Enterprises Ltd. Dublin, Beringen Branch
Business Address: Anthoptstrasse, CH-8222 Beringen, Switzerland
Medical Device(s): FOX plus, 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

29. March 2010
Date


Kai Görling, Manager Quality Assurance

24 March 2010
Date

Attachment to Declaration of Conformity FOX plus PTA Catheter, ID No. 10-011

Usable length 50 cm

Balloon diameter	Balloon length						
	20	30	40	60	80	100	120
3	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-
5	82360-01	-	82361-01	-	-	-	-
6	82362-01	-	82363-01	-	-	-	-
7	82364-01	-	82365-01	-	-	-	-
8	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-

Usable length 80 cm

Balloon diameter	Balloon length						
	20	30	40	60	80	100	120
3	AP12003	-	AP14003	-	82906-01	-	-
4	AP12004	-	AP14004	AP16004	82907-01	82908-01	82909-01
5	AP12005	AP13005	AP14005	AP16005	AP18005	82910-01	82911-01
6	AP12006	AP13006	AP14006	AP16006	AP18006	82912-01	82913-01
7	AP12007	AP13007	AP14007	AP16007	AP18007	82914-01	82915-01
8	AP12008	AP13008	AP14008	AP16008	AP18008	-	-
9	AP12009	AP13009	AP14009	AP16009	-	-	-
10	AP12010	AP13010	AP14010	AP16010	-	-	-
12	AP12012	AP13012	AP14012	AP16012	-	-	-

Usable length 135 cm

Balloon diameter	Balloon length						
	20	30	40	60	80	100	120
3	AP22003	-	AP24003	-	82916-01	-	-
4	AP22004	-	AP24004	AP26004	82917-01	82918-01	82919-01
5	AP22005	AP23005	AP24005	AP26005	AP28005	82920-01	82921-01
6	AP22006	AP23006	AP24006	AP26006	AP28006	82922-01	82923-01
7	AP22007	AP23007	AP24007	AP26007	-	82924-01	82925-01
8	AP22008	AP23008	AP24008	-	-	-	-
9	AP22009	AP23009	AP24009	-	-	-	-
10	AP22010	AP23010	AP24010	-	-	-	-
12	AP22012	-	AP24012	-	-	-	-

Authorized Signatory:


 Rainer Schmidt, Sr. Manager Regulatory Affairs

24 March 2010
 Date


 Kai Görling, Manager Quality Assurance

24 March 2010
 Date