

MANUFACTURER'S DECLARATION OF CONFORMITY

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

Reference: Trace No. 10-012
Manufacturer's Name: Abbott Laboratories Vascular Enterprises Ltd. Dublin, Beringen Branch
Business Address: Anthoptstrasse, CH-8222 Beringen, Switzerland
Medical Device(s): FOX sv, 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 FOX sv PTA Catheter, ID No. 10-012

Balloon diameter	2.0mm	2.5mm	3.0mm	4.0mm	5.0mm	6.0mm
Balloon length, shaft length						
15mm, 90cm	n.a.	n.a.	n.a.	821585401	821685401	n.a.
20mm, 90cm	821445401	823735401	821505401	821605401	821705401	821805401
30mm, 90cm	821465401	823755401	821525401	821625401	821725401	n.a.
40mm, 90cm	821485401	823775401	821545401	821645401	821745401	821845401
60mm, 90cm	821985401	823795401	821565401	821665401	821765401	821865401
80mm, 90cm	829465401	829495401	829525401	829555401	829585401	829615401
100mm, 90cm	829475401	829505401	829535401	829565401	829595401	829625401
120mm, 90cm	829485401	829515401	829545401	829575401	829605401	829635401
15mm, 135cm	n.a.	n.a.	n.a.	821575401	821675401	n.a.
20mm, 135cm	821435401	823725401	821495401	821595401	821695401	821795401
30mm, 135cm	821455401	823745401	821515401	821615401	821715401	n.a.
40mm, 135cm	821475401	823765401	821535401	821635401	821735401	821835401
60mm, 135cm	821975401	823785401	821555401	821655401	821755401	821855401
80mm, 135cm	829645401	829675401	829705401	829735401	829765401	829795401
100mm, 135cm	829655401	829685401	829715401	829745401	829775401	829805401
120mm, 135cm	829665401	829695401	829725401	829755401	829785401	829815401
15mm, 150cm	n.a.	n.a.	n.a.	831575401	831675401	n.a.
20mm, 150cm	831435401	833725401	831495401	831595401	831695401	n.a.
30mm, 150cm	831455401	833745401	831515401	831615401	831715401	n.a.
40mm, 150cm	831475401	833765401	831535401	831635401	831735401	n.a.
60mm, 150cm	831975401	833785401	831555401	831655401	831755401	n.a.
80mm, 150cm	839645401	839675401	839705401	839735401	n.a.	n.a.
100mm, 150cm	839655401	839685401	839715401	839745401	n.a.	n.a.
120mm, 150cm	839665401	839695401	839725401	839755401	n.a.	n.a.

Authorized Signatory:


 Rainer Schmidt, Sr. Manager Regulatory Affairs

24 March 2010
 Date


 Kai Görling, Manager Quality Assurance

24 March 2010
 Date