



National Standards Authority of Ireland

Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

InterVentional Technologies Europe Ltd

**Lisnenan
Letterkenny
Co. Donegal
Ireland**

to the Product Family

Peripheral Cutting Balloon™ Catheters

*on the basis of examination under the requirements of Annex V, Section 3.2 of Directive 93/42/EEC.
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product family is hereby authorised.*

Registration Number:	252.192
Original Approval:	15 July 1996
Last Amended on:	18 July 2008
Remains valid until:	14 July 2011

Signed:

Paddy Breen – Director of NSAI Client Services

Issued on 28 July 2008

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI

National Standards Authority of Ireland, Glasnevin, Dublin 9, Ireland.



National Standards Authority of Ireland

Attachment to Certificate 252.192 dated 15 July 1996

This Certificate covers 22 model(s)

Model Reference	Detail
BPM120015B	Peripheral Cutting Balloon™ Catheter
BPM125015B	Peripheral Cutting Balloon™ Catheter
BPM130015B	Peripheral Cutting Balloon™ Catheter
BPM135015B	Peripheral Cutting Balloon™ Catheter
BPM140015B	Peripheral Cutting Balloon™ Catheter
BP505020B	Peripheral Cutting Balloon™ Catheter
BP506020B	Peripheral Cutting Balloon™ Catheter
BP507020B	Peripheral Cutting Balloon™ Catheter
BP508020B	Peripheral Cutting Balloon™ Catheter
BP905020B	Peripheral Cutting Balloon™ Catheter
BP906020B	Peripheral Cutting Balloon™ Catheter
BP907020B	Peripheral Cutting Balloon™ Catheter
BP908020B	Peripheral Cutting Balloon™ Catheter
BP1355020B	Peripheral Cutting Balloon™ Catheter
BP1356020B	Peripheral Cutting Balloon™ Catheter
BP1357020B	Peripheral Cutting Balloon™ Catheter
BP1358020B	Peripheral Cutting Balloon™ Catheter
BPM2015140F	Peripheral Cutting Balloon™ Catheter
BPM2515140F	Peripheral Cutting Balloon™ Catheter
BPM3015140F	Peripheral Cutting Balloon™ Catheter
BPM3515140F	Peripheral Cutting Balloon™ Catheter
BPM4015140F	Peripheral Cutting Balloon™ Catheter