



Volcano AtheroMed Inc, 1530 O'Brien Drive, Suite A, Menlo Park, CA 94025

Declaration of Conformity

PRODUCT IDENTIFICATION

Product Name	Catalog Number	Description (Part number)
Phoenix® Atherectomy System (D – Deflecting tip catheter) (ND – Non-deflecting tip tracking catheter)	P18130,	1.8mm x 130cm Phoenix Catheter ND (FG1847)
	P18130K	& System (FG2333)
	P22130,	2.2mm x 130cm Phoenix Catheter, ND (FG1984)
	P22130K	& System (FG2334)
	P24130,	2.4mm X 130cm Phoenix Catheter, ND (FG2938)
	P24130K	& System (FG2990)
	P18149,	1.8mm x 149cm Phoenix Catheter ND (FG2160)
	P18149K	& System (FG2335)
	P22149,	2.2mm x 149cm Phoenix Catheter, ND (FG2162)
	P22149K	& System (FG2336)
	PD22130,	2.2mm X 130 cm Phoenix Catheter, D (FG3061)
	PD22130K	& System (FG3431)
	PD24127,	2.4mm X 127cm Phoenix Catheter, D (FG1728)
PD24127K	& System (FG2337)	
P00633	Phoenix Handle with Wire Support Clip (FG0633,FG1818)	

MANUFACTURER

Name of Company	Address	Representative
Volcano AtheroMed, Incorporated	1530 O'Brien Drive Suite A Menlo Park, CA 94025 USA 1.916.281.2050	Jean Chang Sr Director, Operations and Quality

AUTHORIZED REPRESENTATIVE

Name of company	Address	Telephone/email
Volcano Europe BVBA/SPRL	Excelsiorlaan 41 B-1930 Zaventem, Belgium	+32.2.679.1076 +32.2.679.1079 fax

REGISTRATION INFORMATION

Notified Body and ID #	CE or ISO Certificate number
British Standards Institution - 2797	CE 542904
Quality Management System- ISO 13485: 2016	FM 542771

CONFORMITY ASSESSMENT

Device classification, Per Annex IX	Route to compliance
Class IIa Rule 9 Catheters/Handle Class IIa Rule 7 Wire Support Clip (FG1818)	Annex V and VII of MDD 93/42/EEC Council Directive

Volcano AtheroMed Inc. declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices (including the amendment per Directive 2007/47/EC) as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jean Chang, Sr Director, Operations & Quality

SIGNATURE:

