



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 Guidewire	PG14300LF	Phoenix Guidewire, 0.014" X 300cm, Light Support Floppy Tip (OFG2524)

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 6 Phoenix Guidewire (PG14300LF)	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:** \_\_\_\_\_

