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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, P18130K P22130, P22130K P24130, P24130K P18149, P18149K P22149, P22149K P15149, P15149K PD22130, PD22130K PD24127, PD24127K PD24130, PD24130K P00633	1.8mm x 130cm Phoenix Catheter ND (FG1847) & System (FG2333) 2.2mm x 130cm Phoenix Catheter, ND (FG1984) & System (FG2334) 2.4mm X 130cm Phoenix Catheter, ND (FG2938) & System (FG2990) 1.8mm x 149cm Phoenix Catheter ND (FG2160) & System (FG2335) 2.2mm x 149cm Phoenix Catheter, ND (FG2162) & System (FG2336) 1.5mm x 149cm Phoenix Catheter, ND (FG2414) & System (FG3952) 2.2mm X 130 cm Phoenix Catheter, D (FG3061) & System (FG3431) 2.4mm X 127cm Phoenix Catheter, D (FG1728) & System (FG2337) 2.4mm x 130cm Phoenix Catheter, D (FG3926) & System (FG3953) 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.

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In accordance with Article 12 of MDD 93/42/EEC Council Directive 93/42/EEC for Medical Devices (including the amendment per Directive 2007/47/EC) Volcano AtheroMed, Inc. declares the following:

- Mutual compatibility of the devices has been verified,
- Systems are packaged by Volcano AtheroMed and includes relevant instruction for use,
- The process of kitting of the systems is subjected to appropriate methods of control and inspection.

COMPANY REPRESENTATIVE: [redacted]