



# Declaration of Conformity

PRODUCT IDENTIFICATION		
<b>Product name</b>		<b>Model/number</b>
VBMax Pulmonary Function Filter		VBMax Standard – 156xxx VBMax e-Series – 146xxx VBMax s-Series -- 136xxx
MANUFACTURER		
<b>Name of company</b>	<b>Address</b>	<b>Representative</b>
A-M Systems, LLC	131 Business Park Loop Sequim, WA 98382 USA	Robert Thompson
AUTHORIZED REPRESENTATIVE		
<b>Name of company</b>	<b>Address</b>	<b>Telephone/email</b>
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com
CONFORMITY ASSESSMENT		
<b>Device classification</b>	<b>Route to compliance</b>	<b>Standards applied</b>
Class IIa Rule 2	Annex V of MDD 93/42/EEC Council Directive	ISO 14971 ISO 13485 BS EN 980 BS EN 1041
REGISTRATION INFORMATION		
<b>Notified Body and ID #</b>	<b>CE certificate number</b>	
BSI, 0086	CE 533831	

A-M Systems declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Mr. Robert J. Thompson

**TITLE:** Quality Manager    **SIGNATURE:** 

**DATE:** 05/06/2017

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