



# Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
Paper Mouthpieces	1621xx 1623xx 1619xx 1626xx 1633xx 1624xx 1622xx 1630xx 1613xx 1682xx 1683xx 1639xx 1627xx 1625xx 1635xx 1628xx 1638xx 1629xx 1637xx	
MANUFACTURER		
Name of company	Address	Representative
A-M Systems, LLC	131 Business Park Loop Sequim, WA 98382 USA	Robert Thompson
AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
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		
Device classification	Route to compliance	Standards applied
Class I Rule 5	Annex VII of MDD 93/42/EEC Council Directive	ISO 14971 ISO 13485 BS EN 980 BS EN 1041

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:** *Robert J. Thompson*

**DATE:** 05/06/2017

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