



Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
Rubber Mouthpiece	1649xx	
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 ISO 15223-1

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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