



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	Molenstraat 15 2513 BH The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax service@emergogroup.com
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class I Rule 5	Annex VII of MDD 2007/47/EEC Council Directive	ISO 14971:2007 ISO 13485:2003 BS EN 980:2008 BS EN 1041:2008

A-M Systems, LLC declares that the above mentioned products meet the provision of the Council Directive 2007/47/EEC for Medical Devices.

COMPANY REPRESENTATIVE: Mr. Arthur B. Green III

TITLE: General Manager **SIGNATURE:**

DATE: 28/03/2011