

Declaration of Conformity

PRODUCT IDENTIFIC	ATION	
Product name		Model/number
Calibration Syringe		1928xx 1926xx 1915xx
		1927xx
MANUFACTURER	PARTY OF A SALES	
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	+31.70.345.8570 - phone
	2514 AP The Hague	+31.70.346.7299 - fax
	The Netherlands	europe@emergogroup.com
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class I	Annex VII of MDD	ISO 14971
Rule 1	93/42/EEC Council	ISO 13485
		1 DO ELLOSO
	Directive	BS EN 980
	Directive	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

SIGNATURE: Plot & Jun TITLE: Quality Manager

DATE: 05/06/2017