EC DECLARATION OF CONFORMITY

Medical Wire & Equipment Co (Bath) Limited as manufacturer of Transwabs®, Transtubes®, Sigma Transwab® , Dryswab™ and Flock Swab variants declare under Article 11 para 2 of Council Directive 93/42/EEC that the production of these Class IIa Sterile devices conform to the relevant procedures laid out in Annex I and V and VII of this Directive. The company as manufacturer of Transwabs®, Transtubes®, Sigma Transwab®, declare under Article 3 of the European Parliament and of the Council Directive 98/79/EC that the production of these general In Vitro Devices conform to the relevant procedures laid out in Annex I and III of this Directive.

The Company as manufacturer of Pernasal, E.N.T., Chlamydia, Trichomonas, Virocult, Sigma Virocult®, Sigma VCM®, Sigma Swab®, Transwabs® variants and Amnicator® declare under Article 11 para 5 of Council Directive 93/42/EEC that the production of these Class 1 Sterile devices conform to the relevant procedures laid out in Annex I and VII of this Directive. The company as manufacturer of Pernasal, E.N.T, Chlamydia, Trichomonas, Virocult, Sigma Virocult®, Sigma VCM®, Sigma Swab®, Amnicator® declare under Article 3 of the European Parliament and of the Council Directive 98/79/EC that the production of these general In Vitro Devices conform to the relevant procedures laid out in Annex I and III of this Directive.

The Company as a manufacturer of Microrings®, Rapid strip tests, Boricons®, Fecons®, Polycons® and Dipkits®, Bloodgrow®, Microloops®,Microstreakers® Selenite Broth declare under Article 3 of the European Parliament and of the Council Directive 98/79/EC that the production of these general In Vitro Devices conform to the relevant procedures laid out in Annex I and III of this Directive.

This applies only to products with the CE mark.

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Medical Device notified body number 0088, the Original products were registered in 1996 sigma swabs were registered in 2010 and Flock swabs were registered in 2011
In Vitro Diagnostic devices were registered in 2002 registration number 000066, Amnicators registered 2013.

All Isolation Transwabs such as MW570, MW504, and MW503 as well as the Neutralising rinse swabs, MW775, MW774 are neither medical devices or In Vitro Devices and therefore do not comply to the above standards.

All the above products are manufactured in accordance with ISO9001:2008 and ISO 13485:2012 Quality Management Systems and the Food and Drug Administration's Quality System Regulations Described in the Code of Federal Regulations 21 CFR part 820.

This Declaration was completed and authorised by: Amanda Nash
Position: Quality Assurance Manager

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