REF: ISO 15189: 2012



Certificate of Sterility and Quality Assurance

PRODUCT	LOT NUMBER	EXPIRY DATE	DATE OF CERTIFICATION
MW170	18F21	30/06/2020	25/06/2018

Transwab® with Amies Medium Plain

Parameter	Specification		Result
Sterilisation Method	Irradiation (Procedure conforms to ISO 11137)		PASSED
pH at 25°C	7.3 +/- 0.3		PASSED
Non-viable count	No more than 2 microorgan fields	PASSED	
Performance Testing	Recovery within specification with a selection of organism accordance with CLSI M40-Pseudomonas aeruginosa Streptococcus pyogenes Haemophilus influenzae Streptococcus pneumoniae Bacteroides fragilis Peptostreptococcus anaerobius Fusobacterium nucleatum Prevotella melaninogenica Propionibacterium acnes Neisseria gonorrhoeae	ns from the following panel, in	PASSED

Product has been manufactured in accordance with ISO 9001:2015 and ISO 13485:2003 Certificate LRQ0939587 A

Product has been manufactured in accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument No. 618

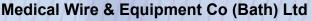
Certificate LRQ0939587 C

Validated performance testing conducted in accordance with: CLSI Quality Control of Microbiological Transport Systems; Approved Standard- Second Edition CLSI document M40-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2014

For and on behalf of Medical Wire & Equipment

Quality Assurance





Corsham, Wiltshire, England, SN13 9RT
Tel: +44 1225 810 361 Fax: +44 1225 810 153
info@mwe.co.uk www.mwe.co.uk

