



## Certificate of Sterility and Quality Assurance

PRODUCT	LOT NUMBER	EXPIRY DATE	DATE OF CERTIFICATION
MW177S	18D04	30/04/2020	13/04/2018

*Sigma-Transwab® with Liquid Amies Medium*

Parameter	Specification	Result
Sterilisation Method	Irradiation (Procedure conforms to ISO 11137)	<b>PASSED</b>
pH at 25°C	7.3 +/- 0.3	<b>PASSED</b>
Non-viable count	No more than 2 microorganisms in 10 high power (1000X) fields	<b>PASSED</b>
Performance Testing	Recovery within specification at 4°C and 25°C tested with a selection of organisms from the following panel, in accordance with CLSI M40-A2 <i>Pseudomonas aeruginosa</i> ATCC@BAA-427 (48 hours) <i>Streptococcus pyogenes</i> ATCC@19615 (48 hours) <i>Haemophilus influenzae</i> ATCC@ 10211 (48 hours) <i>Streptococcus pneumoniae</i> ATCC@ 6305 (48 hours) <i>Bacteroides fragilis</i> ATCC@ 25285 (48 hours) <i>Peptostreptococcus anaerobius</i> ATCC@27337 (48 hours) <i>Fusobacterium nucleatum</i> ATCC@25586 (48 hours) <i>Prevotella melaninogenica</i> ATCC@25845 (48 hours) <i>Propionibacterium acnes</i> ATCC@6915 (48 hours) <i>Neisseria gonorrhoeae</i> ATCC@ 43069 (24 hours)	<b>PASSED</b>

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



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LRQA Notified Body Number  
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