Certificate Number 19473
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 microorganisms in 10 high power (1000X) fields	**PASSED**
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 *Pseudomonas aeruginosa* ATCC®BAA-427 (48 hours) *Streptococcus pyogenes* ATCC®19615 (48 hours) *Haemophilus influenzae* ATCC® 10211 (48 hours) *Streptococcus pneumoniae* ATCC® 6305 (48 hours) *Bacteroides fragilis* ATCC® 25285 (48 hours) *Peptostreptococcus anaerobius* ATCC®27337 (48 hours) *Fusobacterium nucleatum* ATCC®25586 (48 hours) *Prevotella melaninogenica* ATCC®25845 (48 hours) *Propionibacterium acnes* ATCC®6915 (48 hours) *Neisseria gonorrhoeae* ATCC® 43069 (24 hours)	**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

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LRQA Notifed Body Number 0088