



# MICROGEN BIOPRODUCTS

## CERTIFICATE OF CONFORMITY

Name of Product: MICROGEN Staph  
 Product Code: M43(CE)  
 Components: One of each:- M43a, M43b

- All components in this kit comply with current Microgen Bioproducts approved specifications.
- Performance of kit complies with current release specifications.
- Performance of test latex with QC panel gives expected pattern of reactions and complies with current release specifications.

S. aureus (MRSA) MBCC15, positive  
 Staph aureus MBCC193, positive  
 Staph aureus MBCC194, positive  
 Staph aureus MBCC195, positive  
 Staph aureus MBCC197, positive  
 S. aureus (MRSA) MBCC568, positive  
 Staph aureus MBCC693, positive

Staph epid. MBCC198, negative  
 Staph epid. MBCC199, negative  
 Saline, negative

- All components containing human product have been tested for HIV 1/2 Ab, HCV and HbsAg as individual donors and were found to be negative.

### KEY DATA SUMMARY

Component	Part Number	Lot	D.O.M	Expiry	Lot, expiry correct SOP 340	Component PMP reviewed SOP 337
Latex reagent	M43a	10301	2014-09	2016-03	PASS	PASS
Positive Control	M43b	13101	2014-10	2016-01	PASS	PASS
Assembly	M43	10441	2014-10	2016-01	PASS	PASS

Overall:  
Expiry Date:

2016-01

SIGNATURE:

DATE:

21-OCT-14