



**FINISHED PACK
SUMMARY**

FPS M47bCE
Issue Date: 04/2009

BATCH NUMBER 10401

TITLE: MICROSCREEN STREP GROUP B LATEX - CE MARK

MICROGEN BIOPRODUCTS

CERTIFICATE OF CONFORMITY

Name of Product: STREP GROUP B CE
Product Code: M47bCE
Components: One of each: M47bCE,

- 1. This component complies with current Microgen Bioproducts approved specifications.
- 2. Component performance complies with current release specifications.

KEY DATA SUMMARY

Component	Part Number	Lot	Expiry	Lot, expiry correct SOP 340	Component PMP reviewed SOP 337
B Latex	M47bCE	10401	2018-12	Pass	Pass
Assembly	M47bCE	10401	2018-12	Pass	Pass

Overall Expiry Date: 2018-12

Component	Appearance	Fill volume	Sodium Azide	Function
B Latex	Milky white suspension	2.75 ± 0.25 ml	Positive	Agglutinates with group B Strep within 30 seconds

COMPLIES

SIGNATURE: RAU
DATE: 03 / Jul / 2017