



**FINISHED PACK SUMMARY**

FPS M47bCE  
Issue Date: 04/2009

BATCH NUMBER *10001*

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	<i>10001</i>	<i>2018-01</i>	<i>PASS</i>	<i>PASS</i>
Assembly	M47bCE	<i>10001</i>	<i>2018-01</i>	<i>PASS</i>	<i>PASS</i>

Overall Expiry Date:

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: *05/0ct/2016*