

**FINISHED PACK
SUMMARY**

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FPS M47bCE

Issue Date: 10/2017

BATCH NUMBER 11301

TITLE: MICRGEN 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	11301	2020-01	PASS	PASS
Assembly	M47bCE	11301	2020-01	PASS	PASS

Overall Expiry Date: 2020-01

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: *Sajana*

DATE: 01 NOV '18