



FINISHED PACK SUMMARY

BATCH NUMBER 9802

FPS M47dCE
Issue Date: 04/2009

TITLE: MICROSCREEN STREP GROUP D LATEX - CE MARK

MICROGEN BIOPRODUCTS

CERTIFICATE OF CONFORMITY

Name of Product: STREP GROUP D CE
Product Code: M47dCE
Components: One of each: M47dCE, Carton WC2268

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
D Latex	M47dCE	<u>9802</u>	<u>2018-09</u>	<u>Pass</u>	<u>Pass</u>
Assembly	M47dCE	<u>9802</u>	<u>2018-09</u>	<u>Pass</u>	<u>Pass</u>

Overall Expiry Date: 2018-09

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

COMPLIES

SIGNATURE: [Signature]
 DATE: 03 / Jul / 2017