

# **CERTIFICATE OF COMPLIANCE**

BD Vacutainer Systems, Preanalytical Solutions 240 Jefferson Rd Sumter SC 29153-8786 US

Page: 1 of 2

Product Name	:	WINGSET	PBBCS	21X.75	12	LUER
Catalog Number	:	367344				
Batch Number	:	6336789				
Expiration Date	:	2018/11,	/30			

## GMP/MANUFACTURING

BD medical devices are manufactured in accordance with the medical device GMP's (21CFR820). The devices are manufactured in facilities registered with the FDA and the devices are also listed with the FDA.

#### STERILITY

BD products which are labelled as sterile have been processed and released in accordance with Company requirements. The sterilization standards used by BD (irradiation-Cobalt or EO) are based upon acceptable industry guidelines published by the Association for the Advancement of Medical Instrumentation (AAMI). Products will maintain sterility under reasonable conditions of storage and handling, provided the integrity of the packaging is maintained. For those products labelled "sterile fluid path", only the fluid path is sterile.

### PYROGENICITY & TOXICITY

All products which are labelled as non-pyrogenic and/or non-toxic and released for sale by BD are certified to be non-pyrogenic and have passed animal toxicity and/or cytotoxicity tests. For those products labelled "fluid path components are non-pyrogenic (or non-toxic)," only fluid path components are non-toxic or non-pyrogenic.

Sumter Quality Assurance Release date: 2016/12/17 Name: Wendi Geddis

This certificate is produced and controlled electronically and is valid without a handwritten signature.



Γ

# **CERTIFICATE OF COMPLIANCE**

BD Vacutainer Systems, Preanalytical Solutions 240 Jefferson Rd Sumter SC 29153-8786 US

Page: 2 of 2

Product Name	: WINGSET PBBCS 21X.75 12 LUER
Catalog Number	: 367344
Batch Number	: 6336789
Expiration Date	: 2018/11/30

This product conforms to product specification VS59851

allen II

Howie Cullum, QA/RA Manager