



# CERTIFICATE OF COMPLIANCE

Becton, Dickinson and Company  
BD Medical Surgical Systems  
Periferico Luis Donald Colosio # 579  
Nogales SON 84048 MX

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**Product Name** : ANGIOCATH SPECIAL ORN 14GA X 5.25IN  
**Catalog Number** : 382269 **Manufacture Date** : 2019/03/02  
**Batch Number** : 9052700  
**Expiration Date** : 2024/02/29

## REGULATORY COMPLIANCE AND QUALITY SYSTEM

BD Products comply with the regulatory requirements of the region in which these are sold and manufactured.

BD Products sold in the US comply with the current FDA Quality System Regulation 21CFR820. Medical devices are listed with FDA per 21CFR807. Manufacturing sites are registered with FDA per 21CFR807. The devices satisfy FDA pre-market notification requirements per 21CFR807.

BD Products which are CE marked comply with Medical Devices Directive 93/42/EEC and are manufactured within production facilities that comply with the international standard ISO 13485: Quality Systems - Medical Devices - Requirements For regulatory purposes.

## STERILITY

All products which are labeled as #sterile# and released for sale by BD are certified to be sterile as long as the package is unopened and undamaged.

This product is primarily sterilized via EO (Ethylene Oxide). Sterilization cycle development/validation is performed to 10<sup>-6</sup> SAL in accordance with current ISO 11135 guidelines.

## BIOCOMPATABILITY

This product has been evaluated in accordance with ISO 10993 "Biological Evaluation of Medical Devices", and complies with all relevant sections.

## PYROGENICITY

All products which are labeled as non-pyrogenic and released for sale by BD have been tested per United States Pharmacopeia (USP) chapter 85 - Bacterial Endotoxins Test and meets limits as specified in chapter 161- Transfusion and Infusion Assemblies and Similar Medical Devices.

## QUALITY CONTROL TESTING AND RELEASE

Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and signed off by qualified personnel for product release. The released devices meet applicable BD product specification(s).

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## PRODUCT SPECIFIC SPECIFICATIONS

This product complies with the following BD Specification(s):  
PPS-033, ANGIOCATH® SPECIAL CATHETER PRODUCT SPECIFICATIONS

## BD MANUFACTURING SITE

BD Manufacturing site:  
Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V.  
Periferico Luis Donaldo Colosio 579, Colonia Obrera 84048  
Nogales Sonora Mexico

Primary Sterilization site:  
Becton Dickinson Infusion Therapy System Inc.  
9450 South Street  
Sandy, UT 84070

Legal Manufacturer:  
Becton Dickinson Infusion Therapy System Inc.  
9450 South Street  
Sandy, UT 84070

EU Authorized Representative:  
Becton Dickinson Distribution Center  
Laagstraat 57, B-9140 Temse - Belgium

CE Certificate Number: CE01738

Manuel Plazola  
Quality Manager, Nogales