Becton Dickinson Infusion
Therapy Systems Inc. S.A de C.V
Periferico Luis Donaldo Colosio # 579
Col. Obrera C.P. 84048
Nogales, Sonora, Mexico
Tel:(01152631) 314-34-65

BD
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CERTIFICATE OF ANALYSIS

Product Description:	SAF-T-INTIMA PRN YEL 24GA X 0.75IN ROW
BD Item Number:	383318
Lot Number:	8334986
Manufacturing date:	December - 11, 2018
Expiration Date:	2022-11

STERILITY

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

PYROGENICITY

All products labeled as non-pyrogenic have been tested prior to release, per USP chapter 85, and meets limits as stated in chapter 161.

TOXICITY

All materials labeled as non-toxic and released for sale by BD Medical have passed animal toxicity and/or cytotoxicity tests.

QSR (GMP) MANUFACTURING

BD Medical medical devices are manufactured in accordance with the Food and Drug Administration's medical device QSR (21 CFR 820). The device is manufactured in facilities registered* with FDA; the devices are also listed* with FDA. The released devices satisfy BD Medical finished product specifications for product performance.

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Has been subjected to the following test, representative samples were evaluated and were found to fulfill the requirements of the following test:

Test inspection performed	Device Specification	Test/ Inspection Results
Seal between lid and tray	No less than 1/8 in wide	Passed
Package Leaks	No leaks/No Holes	Passed
Product Leaks	No leaks on products	Passed
Ping Test Needle	Maximum force 56.0 gms	Passed
Drag Test Catheter	Maximum force 10.0 gms	Passed
Pull Test Inserter/PVC tubing	Minimum 3.0 lb	Passed
Pull test Inserter/Catheter	Minimum 2.0 lb	Passed
Pull test Adapter/PVC Tubing	Minimum 3.0 lb	Passed
Pull test Needle/Stylet/Hub	Minimum 6.0 lb	Passed
Withdrawal force Inserter	Maximum 1.0 lb	Passed
Withdrawal force PRN	Maximum 1.5 lb	Passed
PRN Removal Torque to Low	Torque test, less than 20 in/oz.	Passed
Visual Inspection	Device is free of visible foreign material	Passed

The above product has been manufactured in accordance with BD Medical specifications, is certified sterile and meets FDA Quality Systems Regulations (Good Manufacturing Practices) requirements.

*Per 21 CFR 807

Manuel Plazola
Manager, Quality Assurance