Becton Dickinson Caribe Ltd.

Indispensable to human health

SOP400-013

QUALITY ASSURANCE CERTIFICATE

STERILITY

All products which are labeled as either "Sterile" or "Sterile Interior" and released for sale by Becton Dickinson Caribe Ltd are certified to be sterile as long as the product package or product is unopened and undamaged. For those products labeled "Sterile Interior" only the product interior is sterile.

PYROGENICITY

All products, which are labeled as non-pyrogenic and released for sale by Becton Dickinson Caribe Ltd, have been tested to company procedures and certified to be non-pyrogenic.

For those products labeled "Fluid Path Components are Non-Pyrogenic" only fluid path components are non-pyrogenic.

GMP/MANUFACTURING

Becton Dickinson Caribe Ltd products are manufactured in accordance with the medical device Good Manufacturing Practices (GMP'S) (21 CFR 820) and comply with Medical Device Reporting (MDR) Regulations (21 CFR 803). All products and manufacturing facilities comply with FDA registration and listing requirements (CFR 807). The released products satisfy Becton Dickinson Caribe Ltd finished product specifications.

Material	Product Description	Batch Number
364902	BD LUER-LOK ACCESS DEVICE Exp.date 2016-13	4016458
N/A	N/A	N/A

E Gonzalez 10/31/14

Quality Assurance Leader or Designee / Date

00-0135-13

Road 916 Km. 0.8 #98 – Cerro Gordo Industrial Park – San Lorenzo, Puerto Rico 00754
Tel. No. (787) 736-0363 – Fax No. (787) 736-6965