CERTIFICATE OF COMPLIANCE

Becton, Dickinson and Company
BD Medical Surgical Systems
Route 7 and Grace Way
Canaan CT 06018-2415 US

Product Name : SYRINGE ORAL 3ML AMBER
Catalog Number : 305210
Batch Number : 6083563

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 21CFR 807.
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.
BIOCOMPATABILITY
This product has been evaluated in accordance with ISO 10993 "Biological Evaluation of Medical Devices", and complies with all relevant sections.
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 specifications.
PRODUCT SPECIFIC SPECIFICATIONS
This product complies with the following BD Specification: SP100061
BD MANUFACTURING SITE
BD Manufacturing site: BD Medical, Route 7 and Grace Way, Canaan, CT 06018, USA
Legal Manufacturer: Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA
EU Authorized Representative: Becton Dickinson Distribution Center, Laagstraat 57 B-9140 Temse- Belgium
CE Certificate Number: 252.308
File name Z1003 CLST_IS_CN16 Revision Date 09/08/2015

Paul Strzepa
Quality Manager, BD Canaan

Creation Date: 2016/04/23 10:35:49