## **W** NIPRO

## NIPRO MEDICAL INDUSTRIES LTD.

2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518 Japan TEL:0276-72-5117 FAX:0276-74-6723

TO: Becton Dickinson Vacutainer System

Attention: BD PAS Quality Assurance Department

Date: Mar 11,2015

## Certificate of Conformance

Purchase Order No.: 6500135969

Reorder No. : 367296 Lot No. : 5B2781

Quantity : 132000 pcs
Date of Manufacture : Mar 2,2015
Expiry : 2018-02
Specification : VS59838

Revision : 19

This is to certify that the item identified herein has been tested in accordance with the specification of VS59838 and meets its requirements. It is further certified that no material/process substitutions were made for any components specified in VS59838.

Test Sample AQL Judgement
Biological Indicator 22 BI/Chamber 0 Passed
Bacterial Endotoxins 10 Set < 0.5EU/mL Passed

Method

Biological Indicator

U.S. Pharmacopeia 37:2014.

<71>Sterility Test

**Bacterial Endotoxins** 

U.S. Pharmacopeia 37:2014.

<85>Bacterial Endotoxins Test

<161>Transfusion and Infusion Assemblies

MonitoringToleranceJudgementProcess parametersWithin limitPassed

Method: ISO11135-1:2007.

Authorized Signature :

Masahiko Akigusa

Quality Control Manager

Nipro Medical Industries Ltd.

Opegusa