## 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 6,2012

## Certificate of Conformance

Purchase Order No.: 4502559959

Reorder No. : 367296 Lot No. : 2B2481

Quantity : 132,000 pcs Date of Manufacture : Feb 27,2012

Expiry : 2015-02 Specification : VS59838

Revision : 15

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 25:2002.

<71>Sterility Test

Bacterial Endotoxins

U.S. Pharmacopeia 25:2002.

<85>Bacterial Endotoxins Test

<161>Transfusion and Infusion Assemblies

Monitoring

Tolerance

Judgement

Process parameters

Within limit

Passed

Method: ISO11135:1994.

Authorized Signature

Hisao Shigetomi

Quality Control Manager

Nipro Medical Industries Ltd.