

NIPRO MEDICAL INDUSTRIES LTD.

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TO: Becton Dickinson Vacutainer System Attention: BD PAS Quality Assurance Department

Date: Mar 25,2013

Certificate of Conformance

Purchase Order No.: 4502871475 : 367296 Reorder No. Lot No. : 3C1381

: 132000 pcs Quantity Date of Manufacture: Mar 14,2013

Expiry : 2016-03 : VS59838 Specification

Revision : 16

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

Method

Biological Indicator

U.S. Pharmacopeia 35:2012.

<71>Sterility Test

Bacterial Endotoxins

U.S. Pharmacopeia 35:2012.

<85>Bacterial Endotoxins Test

<161>Transfusion and Infusion Assemblies

Tolerance Judgement Monitoring Passed Process parameters Within limit

Method: ISO11135-1:2007.

Authorized Signature :

Hisao Shigetomi

Quality Control Manager

Nipro Medical Industries Ltd.