



# NIPRO MEDICAL INDUSTRIES LTD.

2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518 Japan  
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TO : Becton Dickinson Vacutainer System  
Attention : BD PAS Quality Assurance Department

Date : Mar 8,2013

## Certificate of Conformance

Purchase Order No. : 4502842376  
Reorder No. : 367296  
Lot No. : 3B2582  
Quantity : 132000 pcs  
Date of Manufacture : Feb 28,2013  
Expiry : 2016-02  
Specification : VS59838  
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	Sample	AQL	Judgement
Biological Indicator	22 BI/Chamber	0	Passed
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

Monitoring	Tolerance	Judgement
Process parameters	Within limit	Passed

Method :ISO11135-1:2007.

Authorized Signature :

Hisao Shigetomi  
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Nipro Medical Industries Ltd.