



NIPRO MEDICAL INDUSTRIES LTD.

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TEL:0276-72-5117 FAX:0276-74-6723

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

Date : Dec 12,2011

Certificate of Conformance

Purchase Order No. : 4502513061
Reorder No. : 367296
Lot No. : 1L2981
Quantity : 132000 pcs
Date of Manufacture : Dec 1,2011
Specification : VS59838
Revision : 12

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.