



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 : Jan 20,2015

Certificate of Conformance

Purchase Order No. : 6500130822
Reorder No. : 367296
Lot No. : 5A0681
Quantity : 132000 pcs
Date of Manufacture : Jan 9,2015
Expiry : 2018-01
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

Monitoring	Tolerance	Judgement
Process parameters	Within limit	Passed

Method :ISO11135-1:2007.

Authorized Signature :

Masahiko Akigusa
Quality Control Manager
Nipro Medical Industries Ltd.