



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 and Company

Attention : BD PAS Quality Assurance Department

Date : May 7, 2015

Certificate of Conformance

Purchase Order No. : 6500150819
Reorder No. : 367296
Lot No. : 5D2581
Quantity : 132000 pcs
Date of Manufacture : Apr 27, 2015
Expiry : 2018-04
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 38:2015.

<71>Sterility Test

Bacterial Endotoxins

U.S. Pharmacopeia 38:2015.

<85>Bacterial Endotoxins Test

<161>Transfusion and Infusion Assemblies

Monitoring	Tolerance	Judgement
Process parameters	Within limit	Passed

Method : ISO11135:2014.

Authorized Signature :

Masahiko Akigusa

Quality Control Manager

Nipro Medical Industries Ltd.