



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. : 6500144475
Reorder No. : 367296
Lot No. : 5D2681
Quantity : 132000 pcs
Date of Manufacture : Apr 28,2015
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.