

# TERUMOBCT

**Supplier:**

Terumo BCT, Inc.  
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**Manufacturer:**

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Compliance and Quality Administration Department:  
Hitoshi Kuroki

## LOT CERTIFICATE

|                             |                       |                              |                |
|-----------------------------|-----------------------|------------------------------|----------------|
| <b>Product Name:</b>        | TERUFLEX TRANSFER BAG |                              |                |
| <b>Product Code/Cat No:</b> | BB*T100BM             |                              |                |
| <b>Lot number:</b>          | 161221F2              |                              |                |
| <b>Lot size (amount):</b>   | 4,000 sets            |                              |                |
| <b>Sterilization Date:</b>  | 22/12/2016            | <b>Sterilization Method:</b> | Ethylene Oxide |
| <b>Expiry:</b>              | 11/2019               |                              |                |

**Material validation**      Quality of product is validated according to ISO3826-1.

|   |   |                                     |        |
|---|---|-------------------------------------|--------|
| QC specifications and inspection result | (1)Chemical test for PVC material based on internal standards                 | <input checked="" type="checkbox"/> | Passed |
|   | (2)Chemical test for other plastic material based on internal standards       | <input checked="" type="checkbox"/> | Passed |
|   | (3)Function test for PVC container based on internal standards                | <input checked="" type="checkbox"/> | Passed |
|   | (4)Biological test (Bacterial Endotoxin) according to ISO 3826-1              | <input checked="" type="checkbox"/> | Passed |
|   | (5)Microbiological test (Biological Indicator test) according to EN ISO 11135 | <input checked="" type="checkbox"/> | Passed |

Comments results: Lot No. 161221F2      meets all requirements of QC product  
Product Code/Cat No: BB\*T100BM      specification

Release statement :  Lot Released

Date of release determination : 16 / 01 / 2017  
(Day)      (Month)      (Year)



Hitoshi Kuroki,  
Compliance and Quality Administration Department  
Terumo Corporation Fujinomiya Factory

Date of signature : 30 / 01 / 2017  
(Day)      (Month)      (Year)

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