

# TERUMOBCT

**Supplier:**

Terumo BCT, Inc.  
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**Manufacturer:**

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Quality Management Department:  
Makoto Yoshikawa

## LOT CERTIFICATE

<b>Product Name:</b>	TERUFLEX TRANSFER BAG		
<b>Product Code/Cat No:</b>	BB*T100BM		
<b>Lot number:</b>	220324F2		
<b>Lot size (amount):</b>	9,600 sets		
<b>Sterilization Date:</b>	13/04/2022	<b>Sterilization Method:</b>	Ethylene Oxide
<b>Expiry:</b>	02/2025		

**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 ISO 11135 The sterilization assurance level of a validated sterilization process is 1 or less visible microorganisms per 1x10E06 finished products	<input checked="" type="checkbox"/>	Passed


Comments results: Lot No. 220324F2  
Product Code/Cat No: BB\*T100BM

meets all requirements of QC product specification

Release statement :  Lot Released

Date of release determination : 12 / 05 / 2022  
(Day) (Month) (Year)

Date of signature : 13 / 06 / 2022  
(Day) (Month) (Year)

  
Makoto Yoshikawa,  
Quality Management Department  
Terumo Corporation Fujinomiya Factory

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