

TERUMOBCT

Supplier:

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Compliance and Quality Administration Department:
Yoshito Ide

LOT CERTIFICATE

Product Name:	TERUFLEX TRANSFER BAG		
Product Code/Cat No:	BB*T100BM		
Lot number:	201027F2		
Lot size (amount):	9,600 sets		
Sterilization Date:	28/10/2020	Sterilization Method:	Ethylene Oxide
Expiry:	09/2023		

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. 201027F2 meets all requirements of QC product
Product Code/Cat No: BB*T100BM specification

Release statement : Lot Released

Date of release determination : 12 / 11 / 2020
(Day) (Month) (Year)


Yoshito Ide,
Compliance and Quality Administration Department
Terumo Corporation Fujinomiya Factory

Date of signature : 25 / 11 / 2020
(Day) (Month) (Year)