

Product Description	Leucocyte reduction filter with transfusion set	Batch No.	1910067
Type/Code/Ref.	BBF	Mfg. Date	2019.10
Sterile Batch No.	S22002291	Exp. Date	2022.09
Batch Qty.	1000pcs	Reference	"Guide to the Preparation, Use and Quality Assurance of Blood Components", ISO1135-4:2010

Testing Item	Criteria	Result
Part I Physical test		
Specification and integrity	Specification conform to drawing	Pass <input checked="" type="checkbox"/>
	Components integrity verification	Pass <input checked="" type="checkbox"/>
Tubing meas	OD ≥ 2.7mm, WT ≥ 0.5mm	Pass <input checked="" type="checkbox"/>
	Tubing length conform to drawing	Pass <input checked="" type="checkbox"/>
Label	Meet the requirement	Pass <input checked="" type="checkbox"/>
Package	Meet the requirement	Pass <input checked="" type="checkbox"/>
Part II Chemical test		
EO residue	EO residue should less than 1.0mg/set	Pass <input checked="" type="checkbox"/>
Part III Biological test		
Bacterial endotoxin	<20EU/set	Pass <input checked="" type="checkbox"/>
Sterile	Bring up of the sterilized Biological indicator is negative and finished product with no growth of microbial	Pass <input checked="" type="checkbox"/>
Biological Indicator	Spore of Bacillus subtilis(ATCC9372) No growth of microbial after sterilization	Pass <input checked="" type="checkbox"/>
Part IV OTHER QC SPECIFICATION AND INSPECTION RESULT		
1	Chemical test for PVC material	Pass <input checked="" type="checkbox"/>
2	Chemical test for other plastic material based on internal standards	Pass <input checked="" type="checkbox"/>
3	Function test for PVC container according to ISO 3826 and ISO1135-4	Pass <input checked="" type="checkbox"/>



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4	Biological test (pyrogen test) according to ISO10993	Pass <input checked="" type="checkbox"/>
5	Biological test (acute toxicity test) according to ISO10993	Pass <input checked="" type="checkbox"/>
6	Microbiological test (sterility test) according to USP	Pass <input checked="" type="checkbox"/>

Conclusion: The Leucocyte reduction filter with transfusion set with the Lot Number mentioned above has passed the test in accordance with the requirements of "Guide to the preparation, use and quality assurance of blood components "and ISO1135-4

