

Product Testing Report

Report No. C1611008
Report Date: Nov. 22, 2016

Product Description	Leucocyte reduction filter with transfusion set	Sterile Batch No.	161108-1
Type/Code/Ref.	LRF-BB/ BBF2	Mfg. Date	2016.11
Batch No.	161107	Reference	"Guide to the Preparation, Use and Quality Assurance of Blood Components", ISO1135-4:2010
Batch Qty.	1300 pcs		

Testing Item	Criteria	Result
Part I Physical test		
Appearance	Filter chamber shall own smooth surface, keep clean inside and outside, without obvious impurity, weld smooth.	Pass <input checked="" type="checkbox"/>
Particles contamination	The number of particles shall be not exceed the contamination index.(≤ 90)	Pass <input checked="" type="checkbox"/>
Sealing function	It shall no signs of air leakage.	Pass <input checked="" type="checkbox"/>
Linkage strength	The linkage of parts/fittings shall not break under 15N steady axial tension for 15s	Pass <input checked="" type="checkbox"/>
Close-piercing device	It shall be capable of piercing and penetrating the closuer of a fluid container without chip.	Pass <input checked="" type="checkbox"/>
Air-inlet device	The air-inlet device shall be provided with a protective cap over the Close-piercing device or needle	Pass <input checked="" type="checkbox"/>
	The Air-inlet device shall be provided with an air filter	Pass <input checked="" type="checkbox"/>
	When the Air-inlet device is inserted into a rigid infusion container, the air admitted into the container shall not become entrained in the liquid out flow.	Pass <input checked="" type="checkbox"/>
Tubing	It should be Transparent or sufficiently Transparent	Pass <input checked="" type="checkbox"/>
	Inner diameter 3.5+/-0.1mm	Pass <input checked="" type="checkbox"/>
	Outer diameter 5.2+/-0.1mm	Pass <input checked="" type="checkbox"/>
Flow regulator	The flow regulator shall adjust the flow of the blood components between zero and maximum	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		
Oxidizable matter	The difference between testing solution and blank solution on total amount of potassium permanganate solution used[c(KmnO4=0.002mol/L)] shall not exceed 2.0ml	Pass <input checked="" type="checkbox"/>

