

8. Quality Evaluation

The test result shows that this product is in accordance to the intended quality requirement with reference to the YZB/SU-2010 Neonatal phototherapy eye mask medical device registered product standard of Jiangsu Medical device testing center.

Chart 7 Test result

Test item	Requirement	Result	Test report no
Cytotoxicity	No more than 2	2	2010ZC966
Sensitivity response	N/A	N/A	2010ZC966
Skin irritation	N/A	N/A	2010ZC966
Appearance	The periphery and surface of the mask body shall be without defect, dust spot. The edge of the shield pad shall be in good order, heat-sealed by ultrasonic or sewing.	Qualified	2010ZC692
	The periphery and surface of the shield pad shall be without defect, dust spot. The edge of the shield pad shall be in good order.	Qualified	2010ZC692
	The periphery and surface of the eye mask shall be without defect, dust spot. The edge of the shield pad shall be in good order, shield pad shall be pasted on the mask body tightly.	Qualified	2010ZC692
Size	The size shall be in accordance to 6.1.3.3. Specification description	Qualified	2010ZC692
Fasten intensity	When fasten the mask body and shield pad by Heat-sealed by ultrasonic or sewing, It can load the vertical force from an object which weighs 0.5kg.	Qualified	2010ZC692
Blocking blue light	It can block the blue light and other strong visible light well.	Qualified	2010ZC692