

## FOREIGN MATTER AND VISUAL INSPECTION STANDARDS

**PURPOSE:** This specification defines the types, sizes and levels of acceptance for allowable foreign matter and other visual defects for products manufactured for or at Harmac Medical Products, Inc.  
 Note: This applies to C=0 and ANSI/ASQC Z1.4 Sampling Plan

NOTE: Individual QAS requirements may vary based on product use and customer requirements. These standards apply unless otherwise specified. For ANSI/ASQC Z1.4 Sampling Plan use a G-II Normal inspection level.

NO.	CHARACTERISTIC	STANDARD	INSPECTION METHOD	A.Q.L.
I.	Attached Part Flash	0.005" maximum allowed in fluid path or bond port. Elsewhere on part 0.015" maximum.	Examine under normal lighting conditions, holding item 12-15" from eyes. Verify with Optical comparator.	1.0
II.	F/M or loose flash in Fluid Pathway	No visible F/M or loose flash	Examine under normal lighting conditions, holding item 12-15" from eyes.	0.65
III.	Human Hair on Product or in Pouch	No Hair Allowed	Examine under normal lighting conditions, holding item 12-15" from eyes.	0.65
IV.	Fibers on Product or in Pouch	None > .30 mm <sup>2</sup> 1 Max > .20 mm <sup>2</sup> < .30 mm <sup>2</sup> 3 Max > .03 mm <sup>2</sup> < .20 mm <sup>2</sup> Not Counted < .03 mm <sup>2</sup>	Tappi Standard - Visual Normal lighting, holding item 12-15" from eyes.	2.50
V.	F/M or loose flash on Product or in Pouch (specks)	None > .30 mm <sup>2</sup> 1 Max > .20 mm <sup>2</sup> < .30 mm <sup>2</sup> 3 Max > .03 mm <sup>2</sup> < .20 mm <sup>2</sup> Not Counted < .03 mm <sup>2</sup>	Tappi Standard - Visual Normal lighting, holding item 12-15" from eyes	2.50
VI.	Embedded F/M or gels in Product/Components	None > .30 mm <sup>2</sup> 1 Max > .20 mm <sup>2</sup> < .30 mm <sup>2</sup> 3 Max > .03 mm <sup>2</sup> < .20 mm <sup>2</sup> Not Counted < .03 mm <sup>2</sup>	Tappi Standard - Visual Normal lighting, holding item 12-15" from eyes	2.50
VII.	Missing/Loose Components	None-Allowed	Visual - Missing or Loose	0.65
VIII.	Kinked Lines: Complete Kink - opposite sides of tubing touching causing performance failure. (Not permitting fluid flow)	None Allowed	Visual	0.65
IX.	Occlusion: Total or Partial - 25% reduction of tubing ID	None Allowed	Visual	0.65
X.	Packaging and Labels:	No missing or incorrect labels per Harmac Eng. Spec. 1165008	Visual	0.00
XI.	Bonding Spec	S1165003	Visual, Scale and/or Calipers	0.65