

Item/Process	Defect / Fault	Harm	Potential Cause	Risk control measure	Risk Estimation				Risk Evaluation*		New risk? (Y/N)	Note
					Severity	Probability	Risk Index		Pre	Post		
							Risk-Pre	Risk-Post				
<b>Material/component/ packaging procurement</b>	<b>foreign matters</b>	<b>cannot use</b>	<b>contaminate from materials</b>	<b>Inwards goods Inspection/ In process Visual Inspection</b>	<b>4</b>	<b>1</b>	<b>4</b>	-	<b>ACC</b>	-	<b>No</b>	-
	<b>unsterile product due to gas permeable property</b>	<b>infection</b>	<b>insufficient testing when vendor is changed</b>	<b>supplier monitoring</b>	<b>5</b>	<b>2</b>	<b>10</b>	-	<b>ACC</b>	-	<b>No</b>	-
	<b>damaged package</b>	<b>infection</b>	<b>quality of material</b>	<b>Inwards goods Inspection</b>	<b>5</b>	<b>2</b>	<b>10</b>	-	<b>ACC</b>	-	<b>No</b>	-
	<b>unsterile product due to gas quality</b>	<b>infection</b>	<b>quality of gas supply source</b>	<b>supplier monitoring</b>	<b>5</b>	<b>2</b>	<b>10</b>	-	<b>ACC</b>	-	<b>No</b>	-
<b>MOLDING</b>												
Molding	flash	inconvenient use	damaged mold	Routine maintenance	1	2	2	-	ACC	-	<b>No</b>	-
Injection	Short shot	cannot use	unsuitable M/C condition	Routine maintenance and inspection	2	3	6	-	ACC	-	<b>No</b>	-
			M/C problem	Routine maintenance and inspection	2	3	6	-	ACC	-	<b>No</b>	-
	block	cannot use	unsuitable M/C condition	Routine maintenance and inspection	2	3	6	-	ACC	-	<b>No</b>	-
			malfunctioned mold	Routine maintenance and inspection	2	3	6	-	ACC	-	<b>No</b>	-
	<b>broken spike</b>	<b>cannot use</b>	<b>thin wall</b>	In process quality checks	<b>2</b>	<b>3</b>	<b>6</b>	-	<b>ACC</b>	-	<b>No</b>	<b>only set with spike</b>
			<b>out of spec material</b>		<b>2</b>	<b>3</b>	<b>6</b>	-	<b>ACC</b>	-	<b>No</b>	
	wrong dimension	cannot use	unsuitable M/C condition	Routine maintenance and inspection	2	1	2	-	ACC	-	<b>No</b>	-
			malfunctioned mold	Routine maintenance and inspection	2	1	2	-	ACC	-	<b>No</b>	-
			<i>inconsistent quality of material</i>	<i>material inspection</i>	2	1	2	-	ACC	-	<b>No</b>	-
	oil stain	contamination inside body/ toxic	excess use	Routine maintenance and inspection	4	1	4	-	ACC	-	<b>No</b>	-
	leak at weld line or gate	cannot use	blocked air vent of mold	Routine maintenance and inspection	2	3	6	-	ACC	-	<b>No</b>	-
			<b>too small gate</b>	Routine maintenance and inspection	<b>2</b>	<b>3</b>	<b>6</b>	-	<b>ACC</b>	-	<b>No</b>	-
	<b>Movable foreign matter</b>	<b>toxic</b>	<b>damaged mold</b>	Routine maintenance and inspection	<b>4</b>	<b>1</b>	<b>4</b>	-	<b>ACC</b>	-	<b>No</b>	-
	<b>inappropriate hardness</b>	<b>inconvenient use</b>	<b>use of wrong grade of compound</b>	Routine maintenance and inspection	<b>1</b>	<b>1</b>	<b>1</b>	-	<b>ACC</b>	-	<b>No</b>	-
Extrusion	leak	cannot use	mixed foreign material	Routine maintenance and inspection	2	3	6	-	ACC	-	<b>No</b>	-
	<b>kink, flat</b>	inconvenient use	<b>inconsistent quality of material</b>	Material inspection	2	<b>2</b>	<b>4</b>	-	ACC	-	<b>No</b>	-

\* Risk evaluation : ACC = Accept ALARP = As low as Reasonably achievable NACC = Not accept