



## Criteria for Medical Device Classification

Contacting or Inserted Device											
	Intended for Use	Temporary use			Short-term use			Long-term use			
		skin/ cavity	trauma/ tissue	blood circulation/ central circulation	skin/ cavity	trauma/ tissue	blood circulation/ central circulation	skin/ cavity	trauma/ tissue	blood circulation/ central circulation	
<b>P A S S I V E  D E V I C E</b>	1	Device for transportation and storage of pharmaceutical liquid	2	2	3	2	2	3	2	3	3
	2	Device for alteration of blood and body fluids	—	—	3	—	—	3	—	—	3
	3	Device for general medical dressing	1	2	2	1	2	2	—	—	—
	4	Device for functional medical dressing	3	3	3	3	3	3	3	3	3
	5	Implanted surgical instruments	1	2	3	2	2	3	2	3	3
	6	Reusable surgical instruments	1	1	2	—	—	—	—	—	—
	7	Disposable sterile surgical	2	2	3	2	3	3	2	3	3



	device										
8	Implanted device	—	—	—	—	—	—	3	3	3	
9	Device for contraception and birth control	2	2	3	2	3	3	3	3	3	
10	Device for sterilization and cleaning	2	2	2	2	2	2	2	2	2	
11	Other contacting passive device	1	2	3	2	2	3	2	3	3	
<b>Intended for Use</b>		<b>Slight Injury</b>			<b>General Injury</b>			<b>Serious Injury</b>			
<b>A C T I V E D E V I C E</b>	1	Device for treatment through energy	2			2			3		
	2	Device for diagnostic monitoring	2			2			3		
	3	Device for body fluid transportation	2			3			3		
	4	Device for ionized radiation	2			3			3		
	5	Device for active implant	3			3			3		
	6	Other general	2			2			—		



		active device			
<b>Non-Contacting Device</b>					
<b>P A S S I V E</b>	<b>Intended for Use</b>		<b>Nearly Non-impact</b>	<b>Indirect Impact</b>	<b>Vital Indirect Impact</b>
	1	Device for patient care	1	2	—
	2	Other assistant device	1	2	—
<b>A C T I V E</b>	<b>Intended for Use</b>		<b>Nearly Non-impact</b>	<b>Indirect Impact</b>	<b>Vital Indirect Impact</b>
	1	Device for laboratory use	1	2	3
	2	Device for sterilization	1	2	—
	3	Independent software	—	2	3
	4	Other active or active assistant device	1	2	3
<b>I V D</b>	<b>Intended for Use</b>		<b>Low Risk</b>	<b>Medium Risk</b>	<b>High Risk</b>
	1	Reagent box	1	2	3

R E A G E N T	2	Calibrator	—	2	3
	3	Quality control	—	2	3
	4	Reagent	1	2	3
	5	Micro-organism culture medium	1	2	—
	6	Sample Handler	1	2	3
	7	Staining fluid	1	—	—

**Instructions for Use:**

1. This table is an appendix to *Provisions for Medical Device Classification* and applies to the classification of specific products. The mark “-” indicates that there is no such classification yet.
2. The number as “1”, “2”, “3” represents Class I , II , III respectively.