



GENERAL PRINCIPLES OF GROUPING

1. General medical devices can be grouped into one of the following four categories and can be submitted in one application for medical device registration:

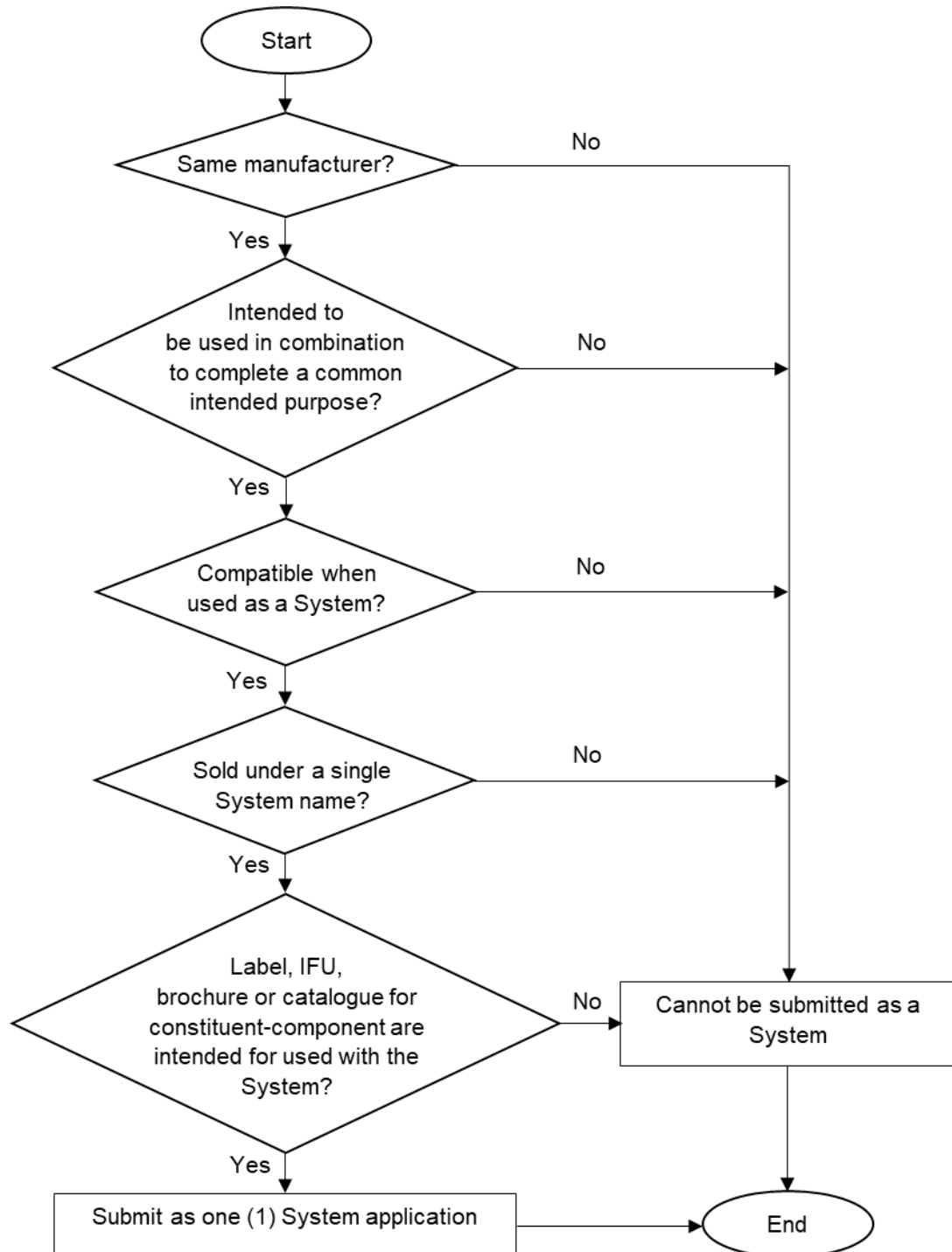
- a) SINGLE;
- b) SYSTEM;
- c) FAMILY;
- d) SET

2. For further explanation, kindly refer to the reference below:

NO.	TITTLE	LINK
1.	GUIDANCE DOCUMENT	General Medical Device-Grouping MDA/GD/0005
2.	SYSTEM	Flowchart for System (Attachment 1)
		Video manual https://www.youtube.com/watch?v=rPbpqaxCx3s
3.	FAMILY	Flowchart for Family (Attachment 2)
		Video manual https://www.youtube.com/watch?v=xil55ZLL4E8
4.	SET	Flowchart for Set (Attachment 3)
		Video manual https://www.youtube.com/watch?v=WPHy98EJWIk

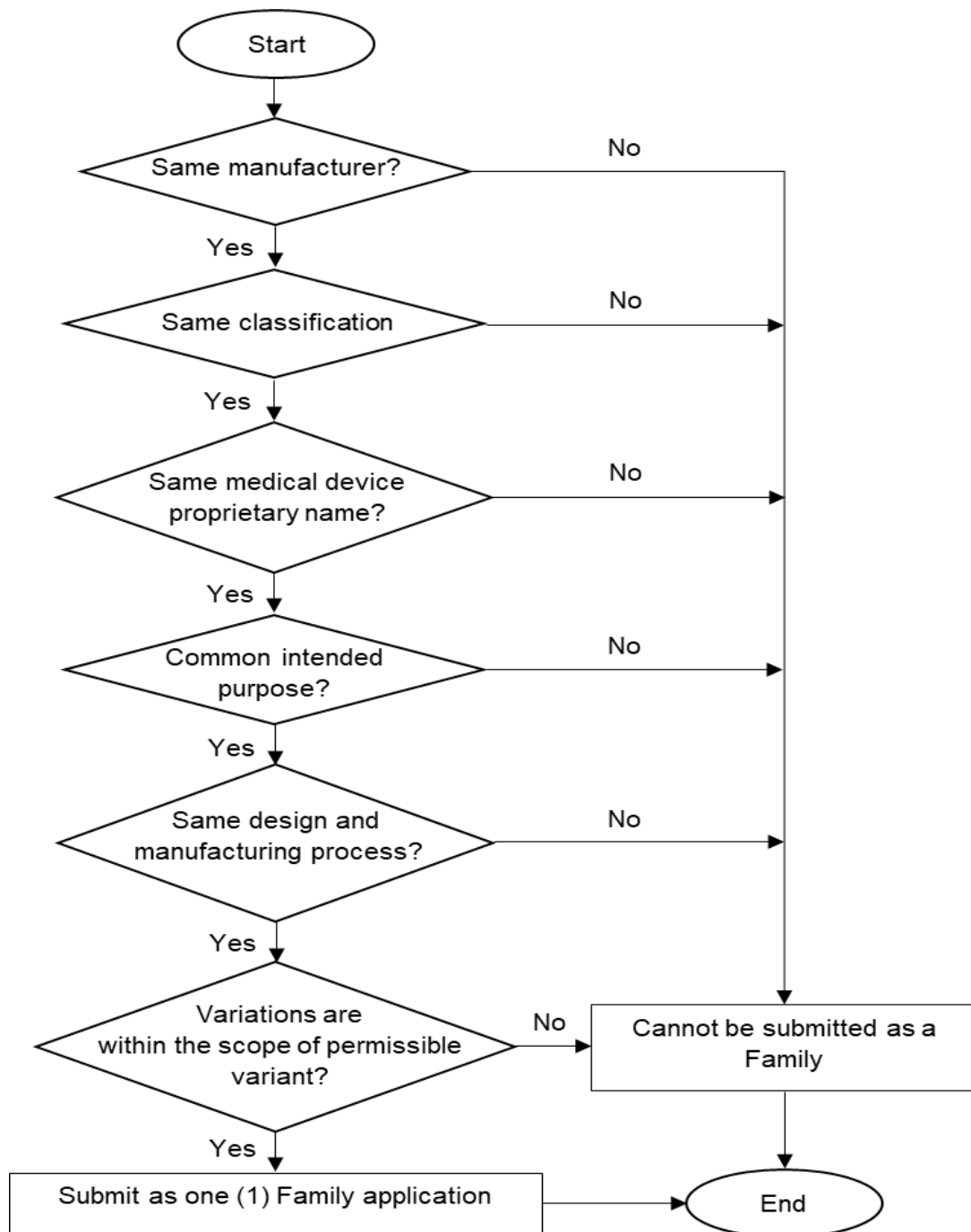
Attachment 1

Decision Flowchart for Grouping of Medical Devices as a SYSTEM



Attachment 2

Decision Flowchart for Grouping of Medical Devices as a FAMILY



Attachment 3

Decision Flowchart for Grouping of Medical Devices as a SET

