APPENDIX 2: ANCILLARY MEDICAL DEVICE DOSSIER REQUIREMENT FOR DRUG-MEDICAL DEVICE COMBINATION PRODUCT

The following classification for the ancillary medical device component based on the risk classification of medical device shall be required for the submission of the dossier:

a. Class B
b. Class C
c. Class D

Refer to MDA/GD-04 The Rule of Classification for General Medical Device.

Table 3: General Requirements for Ancillary Medical Device Dossier

Part	**Section**	**Level Of Risk Classification Of Ancillary Medical Device Component**		
		Class B (Low-Moderate Risk)	**Class C (High-Moderate Risk)**	**Class D (High Risk)**
1	Executive Summary	√	√	√
	a) An overview which covers an introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, novel features and a synopsis of the content of the CSDT;	√	√	√
	b)Commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries	√	√	√
	c)Intended uses and indications in its label	√	√	√
	d)List of regulatory approval or marketing clearance obtained including the registration status, intended use and	√	√	√

	indications of the medical device in other countries; copies of certificates or approval letters from each country and declaration on labelling, packaging and instructions for use			
	e)status of any pending applications for regulatory approval or marketing clearance	X	X	√
	f) important safety and performance related information, which shall include :			
	(i) summary of reportable adverse events and field corrective actions;	√	√	√
	(ii) a description of the medical device if the medical device contains animal or human cells, tissues and/or derivatives thereof, rendered non-viable cells, tissues and/or derivatives of microbial or recombinant origin and/or irradiating components, ionising or non-ionising (if applicable)	√	√	√
2	Relevant essential principles and rule used to demonstrate conformity*	√	√	√

*note : The Essential Principles And Rule Used To Demonstrate Conformity shall be prepared in a form of a checklist that is in accordance with Schedule 1, Appendix 1 of Medical Device Regulation 2012. Example of Essential Principles Conformity Checklist can be found in Schedule 2, Table 1 of Medical Device Regulation 2012)

Ancillary Medical Device components that have been approved by recognized countries as specified in Circular Letter No. 2 Year 2014 are allowed to undergo Conformity Assessment by way of Verification prescribed in the Circular Letter.