APPENDIX 3: APPLICATION FORM FOR ENDORSEMENT LETTER OF ANCILLARY COMPONENT FOR THE REGISTRATION OF COMBINATION PRODUCT

KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.moh.gov.my
Email: kkm@moh.gov.my

APPLICATION FORM FOR ENDORSEMENT LETTER OF ANCILLARY COMPONENT FOR THE REGISTRATION OF COMBINATION PRODUCT

CHECKLIST FOR SUBMISSION

DOCUMENTS	COMBINATION PRODUCT		Please tick if the document is attached
	DRUG-MEDICAL DEVICE	MEDICAL DEVICE-DRUG	
Ancillary Medical Device Dossier *(Appendix 1 of Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products)*	/ (not required for ancillary medical device Class A)	X	
Ancillary Drug Dossier *(Appendix 2 of Guideline For Registration of Drug-Medical Device and Medical Device-Drug Combination Products)*	X	/	

Explanatory Notes: [/] – Required; [X] – Not required

For Ancillary Medical Device Components:

The form and supporting documents can be sent either via email or post hardcopy to:

Chief Executive,
Medical Device Authority,
Level 6, Prima 9, Prima Avenue II, Blok 3547, Persiaran APEC,
63000 Cyberjaya, Selangor.
E-mail: combination.product@mda.gov.my

For Ancillary Drug Components:

The form and supporting documents can be sent manually to:

Product & Cosmetic Regulatory Coordination Section,
Centre for Coordination & Strategic Regulatory Planning,
National Pharmaceutical Regulatory Agency.
Lot 36, Jalan Universiti,
46200 Petaling Jaya,Selangor

Note:

1. For ancillary device components – **Frequently Asked Questions (FAQs) on Combination Products by MDA** at http://www.mda.gov.my/

2. For ancillary drug components – refer **Frequently Asked Questions (FAQs) on Combination Products by NPRA** at http://npra.moh.gov.my/

Please complete all information requested. All fields are mandatory unless stated otherwise.	
1. ***APPLICANT DETAILS**	
Name of Applicant:	
NRIC No. / Passport:	Designation:
Name & Address of Company:	
ROC No.:	
City:	State:
Telephone No.:	Fax No.:
Email Address:	
Role of Applicant:	
☐	Product Registration Holder
☐	Manufacturer *Establishment License No.:*
☐	Authorized Representative *Establishment License No.:*
☐	Others (*please specify*):
2. COMBINATION PRODUCT DETAILS *Please provide product packaging label, product catalogue and product insert*	
☐	Drug-Medical Device
☐	Medical Device-Drug
Product Name:	Manufacturer's Name:
Brand/Model:	
Product Description:	
Intended Use/Indication:	

3. ANCILLARY MEDICAL DEVICE DETAILS

(Only applicable to Drug-Medical Device Combination Product)

Name of Medical Device	
Description of Medical Device	
Intended Use of Medical Device	
Brand/Model of Medical Device	
Name & Address of Manufacturer for the Medical Device	

Table 1: List of Configurations

No.	Name of device, accessories, constituent-components, or articles as per product label:	Model	Device Description

Note: If more than one (1) single medical device, please fill out in a separate sheet.

4. ANCILLARY COMPONENT DETAILS

Please provide details of the ancillary component according to the following:

- Ancillary Medical Device Dossier (refer Appendix 1 of Guideline For Registration of Drug-Medical Device and Medical Device-Drug Combination Products)
- Ancillary Drug Dossier (refer Appendix 2 of Guideline For Registration of Drug-Medical Device and Medical Device-Drug Combination Products)

5. ATTESTATION & DECLARATION

I, <Name of applicant>, ID <NRIC No. / Passport >, on behalf of <Name of company>
the product holder/manufacturer/authorize representative of this ancillary component, hereby declare that :

(tick where applicable)

☐ **Drug-Medical Device**:

i. This/these ancillary medical device(s) component is/are according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737).

☐ **Medical Device-Drug**:

i. This ancillary drug component is according to the definition of drug set out in Control of Drugs and Cosmetics Regulations 1984 which is promulgated under Sales of Drugs Act1952.

I hereby attest that the information and attachment provided on this form are accurate, correct, complete and current to this date.

Signature:

Applicant's Name:

Designation :

Date :

Company stamp :