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

Product already registered with MDA/ NPRA:

Yes ☐ Registration Number: _____ No ☐

CHECKLIST FOR SUBMISSION

DOCUMENTS	COMBINATION PRODUCT		Please tick if the document is attached
	DRUG-MEDICAL DEVICE	MEDICAL DEVICE-DRUG	
Ancillary Medical Device: I. Official/ Cover Letter II. Checklist for subbmission of ancillary medical device component (Section 6 of this document) III. Ancillary Device Dossier (1 copy in the form of electronic copy, CD or Thumb Drive) *(Appendix 1 of Guideline For Drug-Medical Device and Medical Device-Drug Combination Products)*	/	X	
Ancillary Drug: I. Official/ Cover Letter II. Checklist of the relevant drug category (Bioloigc Component or Non-Biologic Component) III. Ancillary Drug Dossier (2 copies in the form of electronic copy, CD) *(Appendix 2 of Guideline For 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 manually (hardcopy document with PDF electronic copy on a CD or Thumb Drive) 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 of Regulatory Coordination & Strategic Planning,
National Pharmaceutical Regulatory Agency.
Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz),
46200 Petaling Jaya,Selangor

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 (if applicable)

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

6. CHECKLIST FOR SUBMISSION OF ANCILLARY MEDICAL DEVICE COMPONENT				
Company's Name: **Product Name:** **Medical Device Name:** **Applicant Name:**			**For MDA Use Only:** Submission ID: **MDA/ENL/** Date of Receipt:	
No:	**Sections**	**Y/N/NA**	**ObjectiveEvidence / Name of document**	**For MDA Use Only**
1.	Complete Application Form (Appendix 3) with a cover letter, hardcopy document & electronic copy (CD/Thumb drive)			
2.	Recognised regulatory agencies approval / clearance		Name of regulatory authority:_____ Approval type:_____	
3.	Overview of the Medical Device			
4.	Labelled pictorial representation for the Medical Device			
5.	Description of the accessories			
6.	Instruction of use (IFU) / Product Catalogue / Brochure			
7.	Contraindications, Warnings, Precautions and Potential Adverse Effects related to the Medical Device			
8.	Materials			
9.	Commercial marketing history			
10.	Post Marketing Information			
11.	Summary of design verification and validation documents			
12.	Risk analysis			
13.	Manufacturing information			
14.	Relevant essential principles and rule used to demonstrate conformity			
15.	RM300/RM600 Fee (Bank Draft payable to 'KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN')			

Explanatory note: Please tick Yes (Y), No (N) or NA (not applicable) to indicate that the requested documentation has been included in your submission. Explain responses in further detail and list related attachments under the Objective Evidence/Name of document column.