APPENDIX 4

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 2 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 3 of Guideline For Registration of Drug-Medical Device and Medical Device-Drug Combination Products)*	X	√	
Report and Certificate of Medical Device Safety and Performance Assessment (CAB)	√	X	
Product catalogue	√	X	
For ancillary medical device Class A with measuring function and calibration and metrology report shall be provided.	√	X	
For ancillary medical device Class A supplied sterile, validation report shall be provided.	√	X	

The form and supporting documents can be sent either via email (in PDF format) or post to:

For Ancillary Medical Device Components	**For Ancillary Drug Components**
Chief Executive, Medical Device Authority, Level 5, Menara Prisma, Persiaran Perdana, Presint 3, 62675 Putrajaya. E-mail: mdb@mdb.gov.my	Secretary, Drug Control Authority, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor. E-mail: helpdesk@npra.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*):
**Note:The application for obtaining endorsement letter and combination product registration must be submitted by the same applicant*	
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:	
Medical Device Grouping:	
Medical Device Description:	
Brand/Model:	
Intended use of the device:	
Manufacturer's Name:	
Class : *(According to Guidance Document GD-04: The Rules of Classification For General Medical Devices)*	
Grouping List :	**(Not Applicable to single medical device)**

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 2 of Guideline For Registration of Drug-Medical Device and Medical Device-Drug Combination Products)
- Ancillary Drug Dossier (refer Appendix 3 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).

ii. The device(s) conform(s) to all relevant essential principles for safety and performance, set out in the Appendix 1 of Third Schedule of the MDR 2012.

☐ **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 :