Checklist Dossier requirements Medical Device
Initial and reconsultation procedures

General instruction module 1:

Documents that are to be located in module one according to the below validation checklist that cannot be included in the eCTD can be include in a separate folder in the CESP submission.

Please name the folder: Module 1_ additional documents Notified Body. The names of the documents and the format should still follow the names and numbers as indicated in the validation checklist.

Version March 2024

Sections granulation	Subject	Required format[1]			MEB comments
		PDF	Searchable pdf[2]	Word (.docx)	
Module 1	**New applications and reconsultation procedures:**				
1.0	Signed cover letter	X			
1.0	Table of contents for module [1]	X			
1.2	General description of the medical device		X	X	
1.2	Scientific explanation that the action of the medicinal substance or human blood derivative incorporated in the medical device is only ancillary to that of the device in line with MDCG 2022-5 or MEDDEV		X	X	
1.2	Application form[3]		X		
1.2	QP declaration on GMP compliance for the active substance or justification for its absence	X			
1.2	GMP certificates for the manufactures of the substance used as ancillary substance in the device	X			
1.2	In case of an ASMF: letter of access[4]	X			
1.2	In case of a CEP: this should be submitted	X			
1.2	TSE statement (if applicable)	X			
1.3.1	Labelling (technical data sheet)		X	X	
1.3.2	Instructions for use (IFU) (version number/date clearly indicated in proposed IFU)		X	X	
1.4.1	Declaration and CV from qualified experts: Quality	X[5]			
1.4.2	Declaration and CV from qualified experts: Non-clinical	X[5]			
1.4.3	Declaration and CV from qualified experts: Clinical	X[5]			
1.8.2.	Risk management system (if applicable)		X		
Additional data	Summary of safety and clinical performance (SSCP)		X[6]	X[6]	

Sections granulation	Subject	Required format[1]			MEB comments
		PDF	Searchable pdf[2]	Word (.docx)	
Additional data	Report on usefulness [7]	X[5] [6]	X[6]	X[6]	

[1] If multiple file formats are indicated, all should be submitted.
[2] Pdf should not be protected.
[3] Submission of a range of products should have been agreed by the MEB prior to submission, refer to annex 1 'criteria for acceptable range of products'.
[4] Access should be given to the MEB and if the assessment of the ASMF restricted part needs to be shared with the Notified body, access should also include the respective Notified body.
[5] Signed and dated
[6] In case the final version is not yet available, the draft version can be submitted. In this draft version should at least contain the confirmation that a positive outcome for the medical device component is expected and the NBs assessment of the SSCP and IFU. Please notify the MEB about the draft version in the cover letter and mention when the final version will be submitted.
[7] The usefulness report must also cover assessment of the instructions for use (IFU)

Sections granulation	Subject	Required format[1]			MEB comments
		PDF	Searchable pdf[2]	Word (.docx)	
Module 1:	**Additional requirements for reconsultation submissions**				
1.2	Proof of CE certification	X			
1.3.2	IFU with tracked changes since the initial agreed IFU text by the (respective) Agency, with a tabular overview of all changes (Date, description of the change, assessment by NB/Agency (Y/N) and the outcome.		X	X	
Additional data	A tabular overview of all changes (including administrative changes) following the initial consultation containing: - Date when the revision was issued; - Description of the main changes; - Assessment by NB/Agency (Y/N)); - Classification of change (minor= insignificant/major = significant) Or a declaration that no changes have been made.		X	X	
Additional data	All assessment reports of the initial consultation (if assessed previously under Medical Device Directive 93/42/EEC).	X			

Sections granulation	Subject	Required format[1]			MEB comments
		PDF	Searchable pdf[2]	Word (.docx)	
Module 2	**Overview and Summaries**				
2.3 eCTD, see EMA guidance:	Quality overall summary: (relevant parts) for the ancillary medicinal substance.		(e)CTD[8]	X	
2.4	Non-clinical overview		X	X	
2.5	Clinical overview		X	X	
2.6	Nonclinical written and tabulated summaries		X	X	
2.7	Clinical written summaries, CTD granulation for: – Clinical pharmacology; – Clinical efficacy; – Clinical safety.		X	X	
2.7	Summary of cumulative safety including all information on adverse events/ adverse reactions/ calamities based on post-marketing experience; estimation of pre- and post-marketing patient exposure, related ADRs, regulatory actions.		X	X	
Module 3	**Quality**				
3.1	Table of contents		X		
eCTD, see EMA guidance:	Body data		(e)CTD[8]		
eCTD, see EMA guidance:	ASMF (please refer to EMA guideline on ASMF)		(e)CTD[8]		
3.3	Literature references	X[9]			

[8] eCTD preferred, CTD acceptable.

[9] Each publication should be provided as separate PDF file, preferably named "<author>-<publication year>"

Sections granulation	Subject	Required format[1]			MEB comments
		PDF	Searchable pdf[2]	Word (.docx)	
Module 4	**Non-Clinical**				
4.1	Table of contents		X		
4.2	Study reports		X[10]		
4.3	Literature references	X[9]			
Module 5	**Clinical**				
5.1	Table of contents		X		
5.2	Tabular listing of studies		X	X	
5.3.5.3	All versions of the clinical evaluation report.		X	X	
5.3.5	Study reports	X			
5.3.6	Post marketing study report		X		
5.4	Literature references	X[9]**Fout! Bladwijzer niet gedefinieerd.**			

[10] Searchable pdf preferred, pdf acceptable.

1 Annex 1: Criteria to be met for an acceptable range of products

Devices can only be submitted as a range of products if compliant to all conditions below:

The following aspects should be equal over the entire range	**Examples of reasons to submit separately**
intended use as specified in the Instructions For Use. Differences in therapeutic indication can be accepted	
route of administration	• subcutaneous vs. intramuscular injection. • Intra- vs extra-ocular injection. • Internal wounds vs. external wounds.
concentration of the ancillary substance	• solution with 10 % vs. 1 % ancillary substance.
composition of the matrix/coating which is used to fixate the ancillary substance to the device	• a different kind of binder.
composition of material of the device part on which the ancillary substance is coated or bound.	
(local) exposure to the ancillary substance during use	Changes towards the coated device part, that influence the local exposure towards the ancillary substance in a clinically relevant way, such as: • Addition of other components on top of the coated part of the device, such as helix structures on grafts. • Additional structures on top of impregnated wound dressings.

If any of the criteria above is not met, each device should be submitted separately including its own applicant form.