Overview of documents to be submitted for clinical investigations with medical devices

	Standard research file medical devices	Article 62 / 74.2	Article 74.1	Article 82	Comments
A1	Cover letter	✓	✓	✓	See A1. Cover letter template.
A2	Authorisation from the sponsor	✓	✓	✓	(If applicable)
A2	Authorisation from legal representative EU if sponsor does not hold offices within EU	✓	✓	✓	(If applicable)
B1	ABR form	✓	✓	✓	You are required to complete the ABR form in ToetsingOnline.
B1a	Eudamed form	✓	✓		You are required to submit the Eudamed form while the Eudamed portal is not yet available.
B6	CCMO form notification discontinuation investigation	✓	✓	✓	(If applicable)
C1	Protocol (Clinical Investigation Plan)	✓	✓	✓	
C2	Protocol amendments	✓	✓	✓	(If applicable)
D1	Investigator's Brochure (IB)	✓	✓		Article 74.1: Investigator's Brochure or Instruction for use.
D2	Investigational Medical Device Dossier (IMDD)	✓		✓	See D2. IMDD template. Article 82: The IMDD is required for a clinical investigation with a non CE-marked medical device or for a clinical investigation with a CE-marked medical device used outside the intended use.
D2	EU declaration of conformity		✓	✓	Article 82: The EU declaration of conformity is only required for CE-marked medical devices used within the intended use of the device.
D2	Instructions for use		✓	✓	
D4	Manufacturer's statement on safety and performance of the medical device	✓		✓	See Annex XV, section 4.1 of the MDR. Article 82: This statement is desirable for non CE-marked medical devices or for CE-marked medical devices used outside the intended use.

E1 / E2	Subject information sheet and informed consent form research subjects	✓	✓	✓	
E3	Promotional materials research subjects	✓	✓	✓	(If applicable)
E4	Other informational materials	✓	✓	✓	(If applicable)
E5	Newsletters or letters with study results	✓	✓	✓	(If applicable)
F1	Questionnaires	✓	✓	✓	(If applicable)
F2	Patient diaries	✓	✓	✓	(If applicable)
F3	Patient cards	✓	✓	✓	If the medical device is an implant, you are required to also submit the implant card (see MDR article 18).
F4	Other	✓	✓	✓	(If applicable)
G1	Insurance certificate for WMO research	✓	✓	✓	
G2	Proof of coverage	✓	✓	✓	
H1	CV independent expert				An independent expert (WMO article 9) is not mandatory for clinical investigations falling within the scope of the MDR.
H2	CV coordinating investigator	✓	✓	✓	(If applicable)
I1	List of participating centres	✓	✓	✓	
I2	Research declaration or Site Suitability Declaration	✓	✓	✓	
I3	CVs principal investigators	✓	✓	✓	
I4	Other information per participating centre	✓	✓	✓	(If applicable)

J1	Financial compensation for research subjects	✓	✓	✓	Only applicable when the information in the ABR form is not sufficient.
J2	Financial compensation for investigators and participating centres	✓	✓	✓	Only applicable when the information in the ABR form is not sufficient.
K1	Recommendations other authorities	✓	✓	✓	Such as: expert panel, notified body, registration authority (FDA).
K2	Assessment other EU Member States	✓	✓	✓	(If applicable)
K3	Clinical trial agreements	✓	✓	✓	
K4	Scientific publications	✓	✓	✓	(If applicable)
K5	Data Safety Monitoring Board (DSMB)	✓	✓	✓	(If applicable)
K6	Other information	✓	✓	✓	(If applicable)
K7	Clinical Evaluation Plan (CEP)	✓	✓		In the cover letter you may mention relevant details or a reference to section of the CEP, or you may submit the complete CEP.
K8	Description of the processing of personal data	✓	✓		See MDR, annex XV, section 4.5. You may mention the procedure in the CIP or in a separate document.