Notification of a Clinical Investigation of Medical Devices

(Form 18.11.2019)

To be filed in by the authority
Record number

Name of clinical investigation	
Device(s) to be investigated	
Product class	☐ I ☐ II a ☐ II b ☐ III ☐ AIMD
Name and address of the sponsor	Name
	Address
	City/Address town and country
	Telephone
	E-mail
	Business ID
Address to which invoice should be sent if different from that above	
Name and address of the investigation site/unit (To be filled in separately for each participating unit)	Name
	Address
	City/Address town and country
	Telephone
	E-mail
Investigation plan	Date ____/____ 20____ Appendix 1
Consent of person in charge of the performance of the investigation (from all sites)	Date ____/____ 20____ Appendix 2
Opinion of the Ethics Committee	Date ____/____ 20____ Appendix 3

Name and address of the principal investicator	Name	
	Qualification	
	Address	
	City/Address town and country	
	Telephone	
	E-mail	
Investigation period		
Agreements between the sponsor and the investigator	☐ Yes ☐ No	Appendix 4
Written description to be given to the subjects	☐ Yes ☐ No	Appendix 5
Summary of the features of the device, including appendices	☐ Yes ☐ No	Appendix 6
Date and place		
Signature		
Name in capital letters		
Name and address of the signatory if other than the sponsor	Name	
	Address	
	City/Address town and country	
	Telephone	
	E-mail	
Appendices to the application	☐ Investigation plan (Appendix 1) ☐ Consent of principal investigator of the performance of the investigation (Appendix 2) ☐ Opinion of the Ethics Committee (Appendix 3) ☐ Agreements between the sponsor and the investigators (Appendix 4) ☐ Written description to be given to the subjects (Appendix 5) ☐ Summary of the features of the device, including appendices (Appendix 6)	

Please mail the printed and signed form, including appendices, to the following address:

Finnish Medicines Agency (Fimea)
Medical Devices
P.O. Box 55
00034 FIMEA

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