



To be filled in by the authority
Record number

Name of the clinical investigation	
Device(s) to be investigated	
Product class	<input type="checkbox"/> I <input type="checkbox"/> II a <input type="checkbox"/> II b <input type="checkbox"/> III <input type="checkbox"/> 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/town
	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 investigator	Name	
	Qualification	
	Address	
	City/town and country	
	Telephone	
	E-mail	
Investigation period		
Agreements between the sponsor and the investigator	<input type="checkbox"/> Yes <input type="checkbox"/> No	Appendix 4
Written description to be given to the subjects	<input type="checkbox"/> Yes <input type="checkbox"/> No	Appendix 5
Summary of the features of the device, including appendices	<input type="checkbox"/> Yes <input type="checkbox"/> 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/town and country	
	Telephone	
	E-mail	
Appendices to the application	<input type="checkbox"/> Investigation plan (Appendix 1) <input type="checkbox"/> Consent of principal investigator of the performance of the investigation (Appendix 2) <input type="checkbox"/> Opinion of the Ethics Committee (Appendix 3) <input type="checkbox"/> Agreements between the sponsor and the investigators (Appendix 4) <input type="checkbox"/> Written description to be given to the subjects (Appendix 5) <input type="checkbox"/> Summary of the features of the device, including appendices (Appendix 6)	

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

National Supervisory Authority for Welfare and Health Valvira  
 Medical Devices  
 P.O. Box 210  
 FI-00281 Helsinki