National Agency for Medicines
Medical Devices
P.O. Box 55
FI-00301 HELSINKI

NOTIFICATION OF A CLINICAL INVESTIGATION OF MEDICAL DEVICES

Name of the clinical investigation	Investigation plan appended
Device(s) to be investigated	
Class	I ☐ II a ☐ II b ☐ III ☐
Name and address of the sponsor	Name Address Tel. Fax E-mail
Name and address of the investigation site/unit (to be filled in separately for each participating unit)	Name Address Tel. Fax E-mail
Consent of the person in charge for the performance of the investigation	To be filled in also in multicenter investigations Date | | | | | | appendix
Opinion of the Ethics Committee	To be filled in also in multicenter investigations Date | | | | | | appendix
Name and address of the investigator in charge If a group is in charge of performing the investigation, the address of the contact person shall be given.	Name Qualification Address Tel. Fax E-mail
Investigation period	
Agreements between the manufacturer and the investigators	☐ Yes ☐ No appendix
Written description to be given to the subject	☐ Yes ☐ No appendix
Summary of the features of the divice	☐ Yes ☐ No appendix
Date and signature	Date | | | | | | signature
Name and address of the signed person, if other than the sponsor	Name Address Tel. Fax E-mail
Payment date of the handing charge	Date | | | | | | appendix