**INVESTIGATOR INITIATED STUDY AGREEMENT**

 THIS INVESTIGATOR INITIATED STUDY AGREEMENT (“**Agreement**”) is made valid as of  Xth of Jan 2025), by and between **University Hospital Brno**, having a place of business at Jihlavská 20, 625 00 Brno, Czech Republic, ID: 65269705, represented by Ivo Rovný, MD, MBA, Director (“**Institution**”) and **Maquet Critical Care AB** with offices at Solna, Röntgenvägen 2, 171 06 Stockholm, Sweden (“**GETINGE**”).

Institution and Getinge are hereinafter individually referred to as a “**Party**” and jointly as the “**Parties**.”

RECITALS

Institution, through its employee, xxxxxxx the “**Principal Investigator**”, has, developed a clinical study (the “**Study**”) detailed in the study protocol attached hereto as Exhibit A (the “**Protocol**”) that is of mutual interest and benefit to GETINGE and the Institution. Principal Investigator’s relevant qualifications, including dates, location, extent, and type of experience, are listed in his/her most recent curriculum vitae (CV), which is attached to this Agreement as Exhibit B.

1. The Study “*NIV NAVA vs nasal CPAP as non-invasive ventilatory support in extremely premature neonates – randomised controlled study”*
2. Having reviewed the Protocol defining the Study, Getinge desires to provide Product to Institution and Principal Investigator solely for the purpose of supporting the Institution and the Principal Investigator to perform the Study as described in this Agreement. Further, the Parties desire that Institution will administer the Study at the Institution. Principal Investigator and Institution shall receive and take responsibility for the Product (as further defined herein) contributed by Getinge to the Study and shall use the Product in the Study.
3. The Parties to this Agreement and the Principal Investigator wish to define their collaboration and their responsibilities in relation to the Study and have therefore entered into this Agreement.

THE PARTIES AGREE AS FOLLOWS:

**ARTICLE I**

**Definitions**

“Applicable Laws and Regulations” shall mean all laws and regulations applicable to the Study, the Principal Investigator and/or the Parties, including the approval from the Swedish Ethical Review Authority for the Study. This shall include, without limitation, (i) the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and any applicable act implementing such directive; (ii) the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (the “MDR”), subject to Article 123 of the MDR; (iii) any national legislation applicable to the Study, the Parties, the investigators (including the Principal Investigators), sponsors, personnel supporting the Study and all Study subjects/participants; (iv) Good Clinical Practice (“GCP”) requirements (including the requirements in ISO 14155:2020), including the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects; any applicable privacy laws (including the General Data Protection Regulation EU 2017/679, the “GDPR”); and any applicable anti-corruption and anti-bribery laws applicable to the Study, the Principal Investigator and the Parties.

“Product” shall mean the products (including devices, consumables, software and equipment, as applicable) listed in Exhibit C.

“GDPR” means as defined under “Applicable Laws and Regulations”.

“Intellectual Property” means all current and future inventions, whether or not patentable, all current and future worldwide patent rights, patents, utility models, copyrightable works, copyrights, know-how, software, including source code and object code, compositions of matter, procedures, experimental results and any other current and future intellectual property.

“Protocol” means as defined above and is attached as Exhibit A.

“Study” means as defined above.

“Study Results” shall mean any intellectual property, know-how, information, equipment, technology, research and development data and records, production data, ideas, discoveries, improvements, processes, drawings, trade secrets and the similar conceived, discovered, generated or first reduced to practice in the course of the Study, by Institution or any of its employees or consultants.

**ARTICLE II**

**Responsibilities of Institution and Principal Investigator**

Section 2.01. Study Implementation. Institution shall serve as the sponsor of the Study and Institution shall undertake all responsibility to coordinate the Study pursuant to Applicable Laws and Regulations. Principal investigator and Institution represent and warrant that the Study will be approved pursuant to Applicable Laws and Regulations, including approval from an ethics committee as required under national law of the country where the Study is to be performed. The Principal Investigator and Institution acknowledge and agree that they bear the responsibility to ensure that the Study and use they make of the Product in the Study shall be in accordance with the Protocol and all Applicable Laws and Regulations.

Section 2.02. Use of the Product. Institution and Principal Investigator shall use the Products provided under this Agreement only for the purpose of conducting the Study in accordance with the Protocol and the Ethics Approval (as defined in Section 2.08 f and appended in Exhibit D). The Institution and Principal Investigator further take the responsibility to ensure the scientific validity of any pooling of data obtained from the output of the Product with corresponding data obtained from other manufacturers products.

Section 2.03. Deliverables prior to commencement of the Study. Institution shall provide Getinge with the following documentation (and any subsequent amendments thereto) prior to commencing the Study. Notwithstanding anything to the contrary, Getinge shall have no obligation under this Agreement until such documentation is received by Getinge.

- Final Study Protocol, for which ethics and regulatory (when applicable) approval has been obtained, which shall be included in Exhibit A;

- The Principal Investigator’s most recent curriculum vitae (CV), included in Exhibit B;

- Patient Information and Informed Consent Template compliant with all applicable data privacy laws including the GDPR, for which ethics approval has been obtained; and

- Copy of Ethics Approval, and when applicable, regulatory notification/approval, included in Exhibit D.

Section 2.04. Reports to Getinge

1. *Milestone Completion*: Institution shall provide quarterly written reports on the progress toward completion of milestones described in Exhibit C (“Milestones”), if applicable.

*(b) Final Report*: The Institution/Principal Investigator shall submit a comprehensive written final report of the Study Results (“Final Report”) to Getinge within three hundred sixty-five (365) days (or such longer period as the Parties may agree in writing) after completion or termination of the Study pursuant to Section 2.05 below. Institution shall prepare and maintain records and reports related to the Study as required by Applicable Laws and Regulations. Subject to what is otherwise stated in this Agreement, all documents, protocols, data, know-how, methods, operations, formulas, confidential information and materials connected to the Study shall remain the exclusive property of Institution.

(c) Under no circumstances shall Getinge be responsible for or obligated to provide financial assistance for Institution’s preparation or provision of reports under this Agreement.

Section 2.05. Study Data and Intellectual Property. Institution agrees to inform Getinge promptly in writing of all Intellectual Property resulting from use of the Product in the Study. Institution grants Getinge a first option to acquire an exclusive license to inventions or discoveries related to the Product resulting from the Study. Institution and Getinge will negotiate in good faith to determine the terms of a license agreement as to each item for which Getinge has agreed to license. If Getinge and Institution fail to execute a license agreement within six (6) months after disclosure of the Intellectual Property to Getinge, Institution shall be free to license the Intellectual Property to any party upon such terms as Institution deems appropriate, without any further obligation to Getinge, but not on terms more favorable to such other party than the terms Institution offered to Getinge.

It is understood that existing inventions and technologies of Getinge, Institution and Principal Investigator are separate property, respectively, and are not affected by this Agreement. Any and all intellectual property, know-how, information, equipment, technology, research and development data and records, production data, ideas, discoveries, improvements, processes, drawings, trade secrets and the similar (“**Proprietary Information**”) controlled or owned by each Party prior to the Effective Date (“**Background**”), and any Proprietary Information generated by any of the Parties independently of the Study and controlled or owned by that Party, shall remain the property of such Party and the other Party shall have no rights or interests therein expect as specifically set forth in this Agreement.

Subject to terms of this Section 2.05 and Section 5.01 on Personal data, Getinge, its parents, subsidiaries, affiliates, officers, directors, contractors and representatives thereof (“Getinge Personnel”) shall have the right to receive, access, use, copy and prepare reports based upon Study data generated by the use of the Product and as documented in the Final Report, Study Results and Study data for the purpose of development and/or verification of the Product or for the purpose of complying with Getinge’s legal obligations as a manufacturer of the Product.

Institution and Principal Investigator warrant that the Final Report, and any associated Study Results or Study data provided to Getinge Personnel shall be anonymized. For the avoidance of doubt, Institution is responsible to ensure that the Final Report and any other Study Results or other reports provided to Getinge do not contain any personal data which could identify any Study participants, and any such data, information and reports provided to Getinge shall be adequately de-identified and not include any personal data of Study participants.

Notwithstanding anything to the contrary, Getinge Personnel shall have the right to disclose the Final Report and Study Results and any reports or assessments based thereon, if required by law, regulation or directive, to notified bodies, regulatory agencies and governmental bodies.

Section 2.06. Publication. Institution shall have the right to publish or otherwise publicly disclose Study Results obtained by use of the Product and shall have the final authority to determine the scope and content of any publications originating from the Study. Institution will give Getinge at least 30 days to review the manuscript, presentation or abstract disclosing Study Results obtained by the use of the Product, prior to any publication or presentation. Any such publication or presentation shall acknowledge, as appropriate, the contribution of Getinge, its employees, agents or representatives. It is the responsibility of the Study sponsor to register the Study with the applicable clinical trials data bank (e.g., clinicaltrials.gov or EUDAMED) as required under Applicable Laws and Regulations. As between Institution and Getinge, Institution shall ensure that the Study is registered with the applicable clinical trials data bank. Getinge shall have the right, but not the obligation, to publish or otherwise publicly disclose (e.g. on its website) the existence of the Study as well as Study Results obtained by use of the Product and provided to Getinge by Institution. Notwithstanding the above, to the extent any Intellectual Property results from the Study are included in any publication, the Parties will take steps to protect the rights to the Intellectual Property prior to publication or other public disclosure. If Institution or Principal Investigator publishes Study Results or findings pursuant to this Section 2.06, such publication may be submitted in lieu of the Final Report with the written consent of Getinge.

Section 2.07. Re-assignment of Principal Investigator. If for any reason the Principal Investigator is unwilling or unable to continue to serve as Principal Investigator, the Institution is entitled to designate another employee who is acceptable to Getinge and Institution to serve as the Principal Investigator of the Study. If a substitute Principal Investigator has not been designated within sixty (60) days after the original Principal Investigator ceases his or her services under this Agreement, Getinge may immediately terminate this Agreement upon written notice to the Institution.

Section 2.08. Representations and Warranties**.** Institution represents and warrants, and it is made an express condition of this Agreement, that:

1. Institution is aware that the Product is provided free of charge and/or loaned (as applicable and described in Exhibit C) to the Study by Getinge on the condition that the Study is conducted consistent with Applicable Laws and Regulations.
2. Institution will use and/or borrow (as applicable and described in Exhibit C) the Product only for performing the research assessments for study subjects ventilated with NAVA Technology, and as outlined in accordance with the Protocol and the Ethics Approval.
3. the Study is independently developed, designed, conducted, managed and assessed by Institution and the Principal Investigator and other collaborators of Institution in conducting the Study.
4. Institution has not been offered or paid any remuneration, directly or indirectly, overtly or covertly, in cash or in kind to (i) refer any individual to another person (e.g., physician or hospital) for the furnishing or arranging for the furnishing of any Getinge product or service; or (ii) purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any Getinge product or service.
5. Institution will comply with all Applicable Laws and Regulations in conducting the Study, including but not limited to applicable laws on clinical trials and any applicable privacy regulations.
6. The Study shall be conducted under conditions that respect the rights of the subject and the ethical concerns that apply when conducting research with human beings. In particular, the physical and mental integrity of the subject and his/her privacy and the protection of his/her data will be protected, in accordance with the applicable personal data protection legislation, including the GDPR. Any individual who decides to participate in the Study will receive all the information necessary to understand, without exception, the details and characteristics of the Study, including the possible effects and potential benefits and risks. The Institution further represents and warrants that all enrollment of subjects, including without limitation, written informed consents obtained from Study subjects, will be made in strict accordance with Applicable Laws and Regulations and the written approval of the Study issued by the governing local ethics committee, which approval is attached as Exhibit D hereto (“**Ethics Approval**”).

Section 2.09. Compliance.All Parties understand and agree that, outside of the use of the Product as proposed in the Study, (i) Institution and Principal Investigator are free in their sole and absolute discretion to use or not to use any of Getinge’s products; and (ii) this Agreement, and any consideration paid under it, is not contingent upon, or in any way related to, Institution’s or, Principal Investigator’s use of Getinge products. Further, Institution undertakes to at all times comply with Getinge Code of Conduct, of which Institution acknowledges receipt.

Section 2.10. Amendments to Protocol. If Principal Investigator modifies the Protocol in any way (including but not limited to any amendments that affect the use of the Product, the objectives of the Study, or potential risks to Study subjects), Principal Investigator will promptly inform Getinge. Continued support by Getinge will be contingent on Getinge’s review and acceptance of these changes.

Section 2.11. Regulatory. Principal Investigator and Institution are solely responsible for any and all safety reporting and regulatory obligations associated with the conduct of the Study pursuant to Applicable Laws and Regulations.

**ARTICLE III**

**Getinge's Responsibilities**

 Section 3.01. Technical Assistance. Upon the reasonable request of Institution, Getinge may, at its discretion, provide Institution reasonable standard technical assistance and user training regarding the Product (which shall not include data analytics or support for the review, assessment or interpretation of Product data), but the parties acknowledge that Getinge is not the sponsor of the Study and is not responsible for developing, conducting, managing, or supervising the Study.

Section 3.02. Getinge Assistance. Getinge shall loan or otherwise provide Product only to Institution and Principal Investigator for use in the Study and the Protocol on in accordance with the terms described in this Agreement, and the Product may hence only be used in support of the Study. Under no circumstances shall Getinge’s maximum commitment exceed the limitations set forth in Exhibit C. Institution and Principal Investigator warrant that they will not seek reimbursement or any other compensation for any Study services funded by Getinge, if any is provided, or any Product provided by Getinge.

Section 3.03. Product Support. If discussed in Exhibit C, Getinge may provide a loan of capital equipment and/or software for a reasonable period of time to complete the Study solely to Institution for Principal Investigator (and not to any third parties collaborating in the Study). In order to receive any capital equipment and software, Institution agrees to abide by the terms set forth in Exhibit C and immediately return the equipment and/or uninstall the software (as applicable) at the end of the Study or termination of this Agreement.

The above Product will not be used for any purpose other than the Study. Violation of this term may cause termination of this Agreement.

Section 3.04 No other obligations. Other than the obligations set forth in this Article III of this Agreement, Getinge expressly disclaims and the Parties acknowledge and warrant that Getinge has no involvement, responsibility, obligations or liability related to or arising from the Protocol, the Study and the proposed and/or actual use of the Product pursuant to the Study or this Agreement.

Institution and the Principal Investigator further acknowledge that the Product is only provided or loaned (as applicable) for use by Institution and Principal Investigator and is only to be used in accordance with the Protocol and the Ethics Approval. Any other use of the Product is not authorized by Getinge and shall be at Institution’s and Principal Investigator’s sole risk, responsibility and liability. Under no circumstances will Getinge be responsible or liable for any use of the Product that is not expressly described in the User Manual of the Product.

To the extent Product is used solely by Institution and Principal Investigator and solely as directed in the Product description, the Protocol, the Ethics Approval, the terms of this Agreement and all Applicable Laws and Regulations, and to the extent the Swedish Product Liability Act (*Sw. Produktansvarslagen 1992:18*) applies to Products, Getinge shall be responsible for injuries arising out of such use of Product solely as specifically required under such law.

**ARTICLE IV**

**Term And Termination**

 Section 4.01. Term. Unless terminated earlier in accordance with Section 4.02, the term of this Agreement will be from the date of the last signature will continue in full force until Dec 2028 and all obligations established in this Agreement and the Protocol, including provision of the Final Report to Getinge in accordance with Section 2.03 (b), must be met by such date. This Agreement may be extended or renewed only by mutual written agreement executed by duly authorized representatives of the Parties.

 Section 4.02. Termination Without Cause. This Agreement may be terminated without cause by any Party upon sixty (60) days' prior written notice.

 Section 4.03. Termination for Breach. A Party may terminate this Agreement on thirty (30) days' written notice to another Party if another Party is in material default or breach of any provision of this Agreement; provided, however, that if the Party receiving such notice cures the breach or default within such thirty (30) day period, this Agreement shall continue in full force and effect.

 Section 4.04. Termination for Insolvency. This Agreement may be immediately terminated upon written notice without prejudice to any other rights which the terminating Party may have, whether under this Agreement, in law, equity or otherwise, as follows:

1. By a Party if another Party ceases doing business as a going concern, makes an assignment for the benefit of creditors, files a voluntary petition in bankruptcy, is adjudicated bankrupt or insolvent, files a petition seeking for itself any reorganization, composition, readjustment, liquidation, dissolution, or similar arrangement under any present or future statute, law, or regulation, or files an answer admitting the material allegations of a petition against it in any proceeding, consents to or acquiesces in the appointment of a trustee, receiver, or liquidator of it, or of all or any substantial part of its assets or properties, or if it or its shareholders shall take any action looking to its dissolution or liquidation.
2. By a Party, if within sixty (60) days after the commencement of any proceedings against another Party seeking reorganization, arrangement, readjustment, liquidation, dissolution, or similar relief under any present or future statute, law, or regulation, such proceedings shall not have been dismissed, or if within sixty (60) days after the appointment without such Party's consent or acquiescence of any trustee, receiver, or liquidator of it or of all or any substantial part of its assets and properties, such appointment shall not be vacated.

 Section 4.05. Termination of Study. This Agreement may be terminated immediately by Getinge if Getinge determines its support for the Study is inappropriate, impractical, or inadvisable to continue based on Applicable Laws and Regulations.

 Section 4.06. Effect of Termination. When the Study is terminated, Institution shall immediately return any loaned/unused Product to Getinge or, if applicable, uninstall or permit a Getinge service technician to uninstall any loaned software after the last patient has completed the Study (see Exhibit C). If any uninstallation of software is performed by Institution, Institution shall provide reasonable evidence to Getinge that uninstallation has been completed.

Section 4.07. Surviving Provisions. Section 2.01, 2.02, 2.04, 2.05, 2.06, 2.08, 2.09, 2.11, 3.04, 4.06 - 4.09, and 5.01-5.10 shall survive any expiration or termination of this Agreement.

Section 4.08. Insurance. Institution shall maintain general liability insurance and professional liability insurance in an adequate amount commensurate with and adequate for the Study providing coverage for personal injury (including death) and property damage arising from the Study. Upon request by Getinge, Institution agrees to provide Getinge with a certificate of insurance evidencing such coverage.

Section 4.09. Indemnity and Limitation of Liability.

1. Institution, its parents, subsidiaries and affiliates will indemnify, defend and hold Getinge and Getinge’s parents, subsidiaries, affiliates, directors, officers, members, employees, agents and representatives (“Getinge Indemnitees”) harmless from and against any and all liabilities, damages, losses or expenses incurred by Getinge including, without limitation, reasonable attorney’s fees and litigation expenses, (“Losses”) in connection with any claims, suits, actions, causes of action, demands or judgments arising out of this Agreement or the Study, including but not limited to; (i) any personal injury (including death) related to or arising from the Study; (ii) any personal injury (including death) or property damage caused by the acts or omissions of Institution, the Principal Investigator, other Study institutions, or any Study personnel; and (iii) Institution’s, Principal Investigator’s or Study personnel’s breach of any of Institution’s representation, warranty or obligation under this Agreement.
2. NOTWITHSTANDING ANYTHING TO THE CONTRARY, UNDER NO CIRCUMSTANCES WILL THE PARTIES BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, UNFORESEEN, OR PUNITIVE DAMAGES, OR ANY DAMAGES ARISING FROM LOSS OF USE OR LOST BUSINESS, REVENUE, PROFITS, DATA OR GOODWILL ARISING FROM OR RELATED TO THIS AGREEMENT OR THE STUDY, WHETHER IN AN ACTION IN CONTRACT, TORT, STRICT LIABILITY OR NEGLIGENCE, OR OTHER ACTIONS, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. NO PARTY SHALL HAVE THE OBLIGATION TO INDEMNIFY ANOTHER PARTY FOR ANOTHER PARTY’S NEGLIGENCE OR WILLFUL MISCONDUCT.

**ARTICLE V**

**Miscellaneous**

Section 5.01. Personal Data. “Personal data” means data as defined by Article 4 section (1) of the General Data Protection Regulation (EU 2016/679).

Each Party shall ensure that any personal data relating to Study participants or Principal Investigator and/or research staff participating in the Study, is collected, stored, used, disclosed and transferred in accordance with Applicable Laws and Regulations. The Parties agree to adhere to the principles of medical confidentiality in relation to subjects involved in the Study and to comply at all times with their respective obligations under all data protection applicable laws in relation to this Agreement and the protection of the personal data of subjects and research staff participating in the Study.

The Parties shall maintain appropriate technical and organizational security measures to protect the subjects’ and the research staff’s personal data they process in relation to this Agreement.

Notwithstanding anything to the contrary herein, the reports to be provided to Getinge by Institution in accordance with this Agreement shall be anonymized and thus shall not include any personal data of Study participants/subjects (for the avoidance of doubt, data must be completely anonymized and no individuals should be possible to identify even if using another set of data, e.g. a key code). It is the responsibility of the Institution (and Principal Investigator, as applicable) to ensure that any data included in any reports (including the Final Report) or other information provided to Getinge under this Agreement shall be adequately anonymized and not constitute or contain personal data.

Section 5.02. Notices. Any notice required or permitted to be given under this Agreement shall be in writing and shall be considered given when mailed by pre-paid registered or certified mail, return receipt requested, or delivered by hand, to the Parties at the following addresses (or such other address as a Party may specify by notice hereunder):

If to Institution:

xxxxxx

If to Getinge:

xxxxxx

 Section 5.03. Independent Contractor. The relationship of the Parties to this Agreement is determined solely by the provisions of this Agreement. The Parties do not intend to create any partnership, employment relationship, agency, joint venture, trust or other relationship with duties or incidents different from those of Parties to an arm’s-length contract. Neither Party shall have the power or authority to bind the other Party.

 Section 5.04. Publicity. No Party shall use the name of the other in connection with any products, promotion, or advertising without the prior written permission of the other.

 Section 5.05. Order of Precedence. The terms of this Agreement shall take precedence over other documentation in the interpretation and resolution of disputes concerning this Study.

 Section 5.06. Assignment. No Party shall assign this Agreement to another without the prior written consent of the other Parties; provided, however, that Getinge may assign this Agreement to any of its affiliates or a successor in ownership of more than 50% of the business assets related to this Agreement or the Product. Any other purported assignment shall be void.

 Section 5.07. Severability. In the event a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, and they shall continue in full force and effect.

 Section 5.08. Governing Law and Dispute Resolution. This Agreement shall be governed by Czech law, without reference to its conflicts of law principles.

The Parties shall endeavor to settle possible disputes amicably. Should the attempts to settle the disputes amicable fail, disputes shall be subject to the exclusive jurisdiction of the competent court in the Czech Republic. In the event of a conflict the text of the contract in the Czech language is decisive.

 Section 5.09. Entire Agreement. This Agreement constitutes the entire Agreement among the Parties and supersedes any and all prior agreements, understandings or arrangements, whether oral or written. The Parties may amend or modify this Agreement in such manner as may be agreed only upon a written instrument executed by authorized representative of all Parties.

Section 5.10. Counterparts. This Agreement is executed in two counterparts, of which each Party receives one.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed on their behalf by their duly authorized representatives to be effective on the year and date first above written.

**[Maquet Critical Care AB]**

By: \_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: xxxxx

Title: xxxxx

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

By: \_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: xxxxx

Title: xxxxx

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[Institution]**

By: \_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: Ivo Rovný, MD, MBA

Title: Director

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PRINCIPAL INVESTIGATOR

By signing below I confirm that I have reviewed the Agreement and Exhibits and I understand and accept the responsibilities of the Principal Investigator.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: xxxxx

Title: MD

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**EXHIBIT A**

THE PROTOCOL

Study protocol (version 2) archived as a separate document. Version 2 (2023-06-27) approved by Ethical committee.

**EXHIBIT B**

PRINCIPAL INVESTIGATOR CURRICULUM VITAE

**[signed Jan 21st, 2025]**

Curriculum Vitae 2022

CV archived as a separate document

**EXHIBIT C**

GETINGE ASSISTANCE

The completion date of the Study shall be **December 2028.**

The Milestones are: Expected dates;

Ethics approval **[16/08/2023]**

Regulatory Authority approval **[27/12/2024]**

Last patient completed **[April 2028]**

Final Reports issued **[December 2028]**

“**Expected date**” is defined as the date Getinge expects Institution, through its Principal Investigator, will have completed each milestone. Milestone completion by the Expected date is an essential term of the Agreement.

**Provision (free of charge) and loan of Product for the Study - general**

Getinge is under no obligation to provide any funding or make other type of financial contribution under this Agreement.

Subject to this Agreement, Getinge hereby provides and commits to provide, free of charge, the below listed devices in specified quantities to Institution, solely for the purpose of conducting the Study. Any unused devices (catheters) by the end of the Study shall be returned to Getinge.

Institution and Principal Investigator shall not sell, assign, transfer, rent, lease, sublicense or redistribute any of the Products or provide third parties with access to the Product. Institution and Principal Investigator are not entitled to copy, reverse engineer, disassemble, decompile, derive source code from object code or otherwise derive or attempt to derive other inner workings of the Product in any manner, or separate pieces of the Product, retranslate or process any programs, extract any program parts or otherwise modify the Product or relating documentation. In the event of loss of the Product for any reason, including without limitation theft or irreparable damage to the Product, Institution shall assume the risk of loss.

Institution and Principal Investigator agree that the Product shall be only used in accordance with the relevant Product description and the Protocol, the Ethics Approval, the terms of this Agreement and all Applicable Laws and Regulations. Institution or Principal Investigator shall inform Getinge immediately of any malfunction in the Product and shall support Getinge’s staff or representatives in any repair and service work. Getinge will use reasonable efforts to take appropriate measures in order to correct any possible defect in the Product that has caused the malfunction. However, if in Getinge’s sole opinion the defect cannot be corrected within a short period of time or only at unreasonable costs and/or in a technically demanding manner, each Party shall be entitled to terminate this Agreement with immediate effect, without Getinge incurring any liability. For the avoidance of doubt, Getinge does not assume any responsibility or liability for any repair or service work, as well as any other services or modifications of the Product, carried out by any other party than Getinge.

Except as explicitly stated herein, Getinge shall have no liability whatsoever related to the Product or the use thereof.

The Product will be delivered to the Institution upon signing of this Agreement by all Parties and the duration of the loan/use of the product will be until Study completion date, as stated above. Getinge staff may support installation of and starting up of the Product upon Principal Investigator’s request. In connection with the delivery and commissioning of the Product, Getinge shall at no cost provide training of the Institution’s staff in the handling and maintenance of the Product, upon the Principal Investigator’s reasonable request.

**Specification of Products**

Devices (single-use consumable devices)*:*

|  |  |  |  |
| --- | --- | --- | --- |
| **Product** | **Article number** | **Total number of packages (5-pack)** | **Total number of catheters / associated guidewires** |
| xxxxx  | xxxx | xx | xx |

**EXHIBIT D**
Ethics Approval

**EXHIBIT E**
Regulatory Authority approval