**Agreement on the Conduct of a Post-Market Clinical Follow-Up Study (PMCF-Study) as a Non-Interventional Clinical Trial with a Medical Device**

by and between

**Všeobecná fakultní nemocnice v Praze**

legally represented by xxxxxxxxxxxxxxxxxxxxxx on the basis of Power of Attorney executing department: 2. interní klinika – Klinika kardiologie a angiologie

represented by xxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Project Leader: xxxxxxxxxxxxxxxxxxxxxxxxxxxxx

2. interní klinika – Klinika kardiologie a angiologie VFN a 1. LF v Praze

U Nemocnice 2, 12800, Praha 2.

* ***“Hospital” -***

and

**Resuscitec GmbH,**

Engesserstraße 4a, 79108 Freiburg, Germany

 HRB 707215

represented by its xxxxxxxxxxxxxxxxx

* ***“Principal” -***

Hospital also hereinafter referred to as "**Institution**"; Principal, Institution are hereinafter jointly referred to as "**Parties**". Project Leader is an employee of the Institution and is appointed by the Institution to conduct the PMCF-Study within the scope of his/her official duties and therefore signs this agreement as confirmation of consent, but not as a separate contractual party.

**Preamble**

Principal is a medical device manufacturer and a spin-off of the University Hospital Freiburg. Principal has developed the CARL system (medical devices of risk classes IIa, IIb and III), as a system for extracorporeal cardiac and/or pulmonary support, which is currently undergoing the certification procedure. The certification procedure has been completed in accordance with the medical device regulations by drawing up a declaration of conformity and CE marking of the medical devices, a post-market clinical follow-up study ("**PMCF-Study**") shall be started as a non-interventional clinical trial in accordance with Section 23b of the German Act on Medical Devices (“*Medizinproduktegesetz*” – “**MPG**”) and the Medical Device Regulation (EU) 2017/745 (“**MDR”**). Principal is interested in obtaining information to confirm the safety and efficacy of the CARL system throughout the lifetime of the device under the conditions of everyday clinical practice when used within its intended purpose.

Institution regularly treats patients in need of extracorporeal cardiac and/or pulmonary support according to the intended purpose of the CARL system. Institution intends to use the CARL system in suitable cases for the treatment of such patients as part of their regular care. Institution is willing to make the data and results generated on the occasion of patient treatment available to the Principal within the framework of the non-interventional study covered by this Agreement in accordance with the following provisions.

Now, therefore, the Parties agree as follows:

* + 1. Subject of this Agreement

Subject of this Agreement is the cooperation of the Parties in the conduct of the non-interventional study with the CARL system as described in § 2 of the Agreement.

* + 1. Project and PMCF-Plan
1. Institution shall conduct the non-interventional study in accordance with the PMCF plan “CARL Registry Study” attached to this Agreement as **Exhibit 1**, in such extent that the Institution is only responsible for collection of data in the pCRF and provision of the pCRF to the Principal
2. The treatment of patients within the framework of this non-interventional study is carried out exclusively under consideration of medical considerations within the scope of usual medical practice (standard care). The Project Leader decides freely and on his/her own responsibility how patients are treated. Thus, the decision as to whether patients are included in the non-interventional study is in principle also the sole responsibility of the Project Leader. The Parties agree that there will be no influence on the part of the client regarding the inclusion of patients in the non-interventional observational study. Principal will not impose any requirements for the treatment of the patients.
3. The Parties are in agreement that only those patients can be enrolled in the non-interventional observational study to whom the CARL system is applied within the scope of its intended purpose. The Principal hereby confirms that the CARL System meets all requirements of the MDR and the Czech Act no. 375/2022 Coll., on medical devices.
4. Institution confirms compliance with the PMCF plan in the course of conducting the non-interventional observational study.
5. The Parties are in agreement that the PMCF plan may during the course of the non-interventional observational study be complemented and/or amended by Principal in compliance with applicable laws, without Institution’s approval. Relevant amendments and complements shall become part of this Agreement as soon as they have been communicated to the Institution by the Principal in writing. Significant changes which have an impact on the agreed remuneration must, however, be coordinated with the Institution.
6. Prior to enrolment of the first study participant in the study, the study will be registered, either with (i) www.clinicaltrials.gov or (ii) with another register that meets the requirements of the International Committee of Medical Journal Editors ("**ICMJE**") guidelines for study registration, in either case to the extent required by ICMJE guidelines (as applicable at the time of Study initiation) in order for the study results to be suitable for publication in an ICMJE journal.
7. The occurrence of serious adverse events shall be notified to the Principal without delay.
	* 1. Obligations of Institution
8. Institution agrees to document the treatment of the patients included in the non‑interventional observational study for the time period before and after the performed treatment, and to include such findings of pre-treatment providers, which must be collected and documented anyway within the scope of the current standards regarding documentation.
9. Institution will attempt to achieve the enrolment of 25 patients within a period of 24 months starting from the beginning of the study.
10. Project Leader commits to collect and document all data and findings with due diligence and in accordance with applicable medical quality standards, and to take into account and to comply with all applicable laws and regulations thereby.
11. Project Leader shall inform the Principal after completion of the non‑interventional observational study how many patients were treated with the CARL system during the study period, but did not or could not provide informed consent. This approach is intended to provide the most comprehensive data possible for all patients treated with the CARL system during the study period in order to avoid falsification of the results. For these patients, there will be no transmission of data from the patient file according to § 4.
12. Project Leader shall seek advice from the competent ethics committee with regard to the present non-interventional observational study and potential conflicts of interest. Principal will bear the costs arising thereby.
	* 1. Paper-based Case Report Form (pCRF)
13. Project Leader shall verbally inform each patient participating in the non-interventional observational study about the significance and scope of the non-interventional observational study and seek informed consent, and shall be available to answer any questions the patient may have and respond to them to the extent requested by the patient. The information and Informed consent may be carried out at any time after treatment with the CARL system, but before the end of the study. If the patient is no longer capable of giving consent, the information shall be given to and the consent obtained from those persons who are authorised to give consent to the transfer of the patient's required data. Institution shall use the patient information document attached hereto as **Exhibit 2** for the information and the document attached as **Exhibit 3** for the informed consent. The Principal is responsible for accurateness of the Exhibits 2 and 3 and their accordance with the applicable Laws and PMCF plan. These documents have to be proved by the competent authorities, including ethic committees.
14. The patient information pursuant to Annex 2 and the signed informed consent form pursuant to Annex 3 shall be kept in safe custody at the Institution. At Principal's request, a data protection supervisory authority, the patient or the patient's heirs or potential heirs shall be granted access to the consent form, as well as in the event of an inspection in the context of a court hearing or in the context of independent evidence proceedings. The same shall apply to the relevant pseudonym for the respective patient pursuant to § 4 para. 3.
15. Project Leader is obliged to enter the data specified in the pCRF documentation protocol pursuant to **Exhibit 4** timely and accurately into the paper-based Case Report Form provided by the Principal.

The obligation under the preceding paragraph shall only apply if the patient has consented. In the absence of consent, Institution is prohibited from entering data from the patient into pCRF.

Project Leader shall independently create a pseudonymisation key and keep it securely at the Institution together with the informed consent. Project Leader shall ensure that only pseudonymised data – with regard to the patient – is filed in the pCRF.

1. The Parties agree that the Principal may make minor amendments and/or additions to the pCRF documentation protocol attached as Exhibit 4 at any time without the consent of the Institution being required. Respective amendments as well as complements shall become part of the Agreement as soon as they have been notified to the Institution by the Principal in writing by sending the amended documentation protocol.
2. Institution undertakes to grant the contract research organisation (CRO) novineon CRO GmbH, Friedrich-Miescher-Straße 9, 72076 Tübingen, commissioned by Principal, access to the patient files of the patients enrolled in the non-interventional observational study in order to ensure the data quality of the collected data and to enable a comparison between the collected and the documented data. Corresponding inspections are to be carried out only after prior notification in text or written form on site at the Hospital. In this regard, when including patients in the observational study, Institution undertakes to request the patient’s written consent to make the patient file accessible to the contract research organisation (CRO) commissioned by Principal for the purpose stated in this paragraph 5. In the event that such consent is missing, the third party commissioned by Principal is not entitled to inspect the respective patient file and the obligation arising from sentence 1 of this para. 5 shall not apply. The Principal is responsible for all persons provided monitoring of this study in the Hospital. These persons are obliged to respect operational rules of the Hospital.
	* 1. Data protection
3. To be able to perform the contractual relationship set out in this contract the parties undertake to treat the information to which they have access for the purpose of this contract with complete confidentiality. The confidentiality stipulations contained in these clauses shall remain in force after the end of the contractual relationship or termination of the contract. In the case of training actions, the data of the workers who attend will be treated for the exclusive purpose of the management of the training and administrative actions derived from the same.
4. The parties state that the data and information provided in said document will be processed in accordance with the provisions of the current legislation on data protection and Regulation (EU) 2016/679 of 27 April 2016 (GDPR) and Organic Law (ES) 3/2018, of 5 December (LOPDGDD), with the sole purpose of performance of the contract. Said data will be kept for as long as there is a contractual relationship between the parties. Once the data is no longer necessary for such purpose, the data will be suppressed by blocking it during the time frame established by law, putting technical and organizational measures in place to prevent the processing of the data including its visualization, and being only available to judges, courts, public prosecutor or public administrations, in order to respond to legal duties. Subsequently, after the suppression or blocking period, the data will be erased. There are no plans to communicate the data to third parties, unless there is a legal obligation to do so, or to those providers associated with the parties acting as Data Processors. The contract holders will be informed in advance of any other transfer of data. The Principal declares that data will not be transferred outside the European Economic Area.
5. At any time, the parties may exercise their rights of access to, rectification, erasure and portability of their data and the rights to restrict and object to them being processed, by writing to the address that appears at the top of this contract. If the parties consider that the processing of personal data does not comply with the current legislation, they may lodge a complaint with the supervisory Authority.
6. The Principal considers itself an independent data controller with respect to its processing of personal data regarding patients and reported by the Institution to the Principal according to the PMCF-Study Plan and the Agreement. The Principal declares that it fulfills all obligations set for the controller by the relevant Laws, including information obligations and the processing of personal data of patients in strict accordance with the consent of the data subject and the PMCF-Study Plan. The Principal provide the Hospital with relevant consent of patient with processing personal data within the PMCF-Study.
7. With respect to the PMCF-Study the Institution is the data processor. The Institution remains the controller of personal data collected from the patients with respect to the treatment of the patients pursuant to medical standard of care and applicable legal obligations.
8. The Principal undertakes to personal data confidential and take appropriate technical and organisational security measures to protect personal data against unauthorised or unlawful processing, accidental loss or damage or destruction, to meet the requirements of the GDPR. In assessing the appropriate level of security, the Principal shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purposes of processing and the risks involved for the patients.
9. The Principal shall ensure that its personnel engaged in the processing of personal data are informed of the confidential nature of the personal Ddta, have received appropriate training on their responsibilities, and have executed written confidentiality agreements, or are otherwise subject to professional obligations of confidentiality. The Principal shall ensure that access to personal data is limited to those personnel who perform services in accordance with the Agreement.
10. In the event of a personal data breach or on receipt of any communication, inquiry, request, or complaint from any third party, including a public authority or a patient, relating to the processed personal data, each Party will notify the other Party promptly of personal data breach or any such third party communication.
	* 1. Obligations of Principal
11. Principal is available to the Institution for any queries arising in relation to the conduct of the non-interventional observational study. Respective questions can be sent to or discussed, respectively, under

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1. Principal shall pay the Institution the remuneration agreed in the Agreement for the expenses incurred by the Institution in the context of the conduct of the non-interventional observational study (§ 7 of the Agreement).
	* 1. Provision of Medical Devices for Non-Interventional Observational Study
2. Principal shall provide the Institution with the medical devices listed in **Exhibit 5** of this Agreement for the purpose of conducting the non-interventional observational study. The contracting Parties shall enter into a separate agreement on this. The medical devices shall be delivered by the Principal accompanied by a delivery note. The receipt of the medical devices shall be acknowledged by the Institution in text or written form.
3. During the period of the non-interventional observational study, Institution is entitled to medically use the medical devices for the intended medical indications areas.
4. The provided medical devices, which are not subject to consumption, remain the property of Principal during the entire term of the Agreement and can be reclaimed at any time upon short notice. Institution undertakes to return the medical devices that have not been consumed to the Principal immediately after completion of the non-interventional observational study or to make them available for pick-up. Principal undertakes to collect the remaining medical devices following Institution’s notification.
5. Principal undertakes to provide the information required for the operating of the medical devices and to provide the necessary training and instruction according to applicable Laws. The medical devices required for the conduct of the non-interventional observational study, which are subject to consumption, will be made available to the Institution by the Principal as needed.
6. Principal confirms that the medical devices provided are free of defects upon delivery and that the necessary approvals and certifications for use as a medical device are available. If (hidden) defects are discovered during or after delivery, these shall be notified to Principal in writing without delay.
7. Institution is obliged to treat the medical devices with care and to use and maintain them professionally and properly for the duration of the period of use.
8. Principal shall insure the medical devices during the term of this Agreement against any damage or loss that may arise, for example, due to improper use or theft, at its own expense, also in the event of loan.
	* 1. Remuneration
9. Principal shall pay the Institution as remuneration an amount of EUR 250.00 excl. VAT for each properly completed pCRF documentation protocol. This remuneration shall also cover the administrative effort in relation to the enrolment of the respective patient in the non-interventional observational study, as it arises, e.g., due to the information required for the observational study etc. at the Institution. In case the pCRF documentation protocols are not completed in full, the CRO will check and inform Principal whether a proper data transfer nevertheless exists (e.g. because more data could not be collected in the specific individual case).
10. In the event the documentation effort change more than just insignificantly due to an amendment of the pCRF documentation protocol attached as **Exhibit 4** or the PMCF plan according to § 2 para. 5 initiated by the Principal pursuant to § 4 para. 4, the Parties shall take this into account by adjusting the remuneration adequately. For a corresponding adjustment, a written agreement shall be concluded between the Parties as an amendment to this Agreement.
11. Payment of the remuneration shall be made semi-anuual and only upon receipt of a proper invoice and after Principal has been enabled by the Institution to check the documentation for completeness and plausibility. Principal is obliged to carry out the check in a timely manner.
12. Payments under this Agreement shall be made solely by non-cash transfer to Institution's funds account specified below:

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| --- | --- |
| Account name  | Všeobecná fakultní nemocnice v Praze (General University Hospital in Prague)  |
| Account number  | 34534-24035021 |
| Bank code | 0710 |
| IBAN  | CZ06 0710 0345 3400 2403 5021 |
| Bank name  | Česká národní banka |
| Bank address  | Na Příkopě 28 |
| City, Postal Code, Country  | Prague 1, 115 03, Czech Republic |
| Swift Code  | CNBACZPP |

 Specific symbol: 5221122202

Any remuneration and reimbursement for the Hospital must be paid within 30 days of the day the Principal receives a relevant tax document (invoice).

Reason for payments: Project number [xxxx

1. If services under this Agreement are subject to value added tax, the project partners shall inform the Principal accordingly and take this into account when issuing the invoice in accordance with § 7 para. 3. In this case, Principal shall pay the applicable turnover tax in addition to the agreed remuneration.
	* 1. Rights to Findings and Results of the Non-Interventional Observational Study
2. All rights to the results and data of the non-interventional observational study according to the observation plan shall be owned by Principal, subject to the publication rights of the Institution according to § 10, upon full payment of the agreed remuneration.

1. By way of clarification, the Parties point out that Principal is not entitled to any rights to the patient files themselves. This does not apply to data made available to Principal from the patient file under this Agreement. The Project Leader retains his/her ownership of personal records within the scope of the study.
2. Institution commits to make available to Principal any findings and results relating to the CARL system that are gained, obtained or otherwise achieved during the conduct of the non-interventional observational study.

(a) to the extent as the aforementioned findings and results are limited solely to the study, the Institution shall transfer full rights to the Principal, to the extent legally feasible, in consideration for reimbursement of any costs incurred up to the time of transfer. To the extent a transfer is not feasible, respective rights of use shall be granted to the Principal.

(b) To the extent the aforementioned findings and results, including inventions, extend beyond the project and can also be used in other fields, the Institution shall grant Principal a worldwide non-exclusive, transferable and sub-licensable licence for the field of the project. In this respect, a separate licence agreement shall be concluded with appropriate remuneration for the grant of the licence, which shall include the inventor's compensation. Insofar as Institution does not wish to file an application, Institution shall inform the Principal. Principal shall then be free to file the application (whether in Germany or abroad) in its own name.

(c) Notwithstanding the foregoing provisions, Institution shall be entitled to use all (protectable and non-protectable) results of the research project for academic teaching and research as well as for academic examinations by Institution’s academic personnel (e.g. for doctoral and post-doctoral theses).

* + 1. Non-Disclosure and Confidentiality
1. The Parties undertake to keep confidential for a period of 5 years after disclosure any confidential information of the other party which becomes known in connection with the performance of this Agreement and which at the time of disclosure was either designated as confidential or could reasonably be qualified as confidential by the recipient.
2. All aforementioned findings and results shall be subject to non-disclosure and confidentiality. In order to enable protection of the findings and results (e.g. patent application), the Parties shall keep all findings and results confidential and shall neither publish them nor otherwise make them available to third parties or provide third parties with access to them. The provisions of this paragraph shall apply only to the extent that nothing to the contrary arises from this Agreement, especially in the § 10.
3. The obligation of secrecy or confidentiality shall not apply to such information for which the respective party proves that the information
4. was already known to the public at the time of disclosure; or
5. became publicly known after disclosure, unless due to a breach of this Agreement or a contractual breach by a third party, or
6. was in the other Party's rightful possession at the time of disclosure and was not obtained directly or indirectly by the other Party or by a third party under a confidentiality agreement entered into with the other Party; or
7. was developed by the Party independently of the confidential information received under this Agreement.
8. Upon termination of the Agreement, the Parties shall, upon request, return or transfer all documents containing information covered by this obligation of non-disclosure and confidentiality, unless prohibited by statutory law. Furthermore, this obligation shall not apply to the extent that this is not feasible due to routinely made backup copies of electronic data traffic or - if required for the fulfilment of documentation obligations - to the retention of a copy solely for internal archiving purposes, provided that the confidential information or copies thereof continue to be subject to the obligations agreed herein.

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* + 1. Publication
1. Principal acknowledges Institution’s fundamental right to publish.
2. Manuscripts of intended publications and lectures shall be submitted to Principal for review at least 30 calendar days before the planned publication. Suggestions for changes shall be considered to the extent they do not impair the scientific character or the neutrality of the publication. If no objection has been raised by Principal within 30 calendar days of submission, approval for publication shall be deemed to have been granted.
3. Institution agrees that Principal may use findings and results from the non-interventional observational study for information and publication of any kind.
	* 1. Retention Obligations

The retention obligations of the Parties shall be governed by the statutory provisions; however, the Parties undertake to retain, to the extent permitted by law, the documents related to the non-interventional observational study for a period of at least ten years.

* + 1. Assurance
1. The contracting Parties confirm that the conclusion of the Agreement will not influence any of the Institution’s sales transactions, in particular procurement transactions or pricing, and that there are no expectations in this respect.
2. Furthermore, the Parties confirm that with the conclusion of the Agreement and the services exchanged within the scope of this Agreement no incentive for a preferential use and or recommendations of certain medical devices is intended and will also not be attained.
3. Institution ensures that itself or the persons commissioned by it organise the tasks arising from this Agreement independently, diligently and dutifully in a suitable form and carry them out properly in compliance with the applicable law, in particular the medical device law, the criminal law on corruption, the law on advertising of medical products, the social law, the medical professional law as well as accepted scientific standards. Principal ensures that itself or the persons commissioned by it provide the study under this Agreement independently, diligently and dutifully in a suitable form and carry the study properly in compliance with the applicable law, in particular the medical device law, the criminal law on corruption, the law on advertising of medical products, the social law.
	* 1. Term of the Agreement and Termination
4. This present Agreement shall enter into force upon publication of the Agreement. The Parties agree that the Agreement shall remain in effect until the non-interventional observational study in accordance with the observational plan is terminated, for whatever reason, unless it is terminated prematurely.
5. Principal may terminate the Agreement with immediate effect for good cause. Good cause shall be deemed to exist in particular if
6. the recruitment of patients is not completed within the above-mentioned period (cf. § 3 para. 2) or
7. the marketing authorisation/certification of the investigational medical device is withdrawn or suspended, or the application conditions are changed in such a way that the conduct of the non-interventional observational study would no longer comply with them, or
8. violations of the legal and other provisions applicable to the conduct, or of the observation plan by the project partners and the proper collection and evaluation of data therefore no longer appears to be ensured; or
9. a breach of contractual obligations by Institution and/or the Project Leader is not ended within 30 days following a request to remedy or end the breach of obligations.
10. Institution may terminate this Agreement with immediate effect for good cause. Good cause shall be deemed to exist in particular if Principal fails to end a breach of contractual obligations within 30 days following a request to remedy or end the breach of obligations.
11. Notice of termination shall be given to the other Parties in text or written form.
12. The Parties agree that termination of this Agreement – for whatever reason – shall not affect the Parties' contractual obligations of confidentiality and retention.
13. If the Agreement is terminated during its term, Principal shall remunerate Institution on a pro rata basis for services duly rendered by the Institution as well as for those financial commitments which were duly incurred prior to termination but only become due for payment by Institution after termination.
14. In accordance with Act no. 340/2015 Coll. the Agreement shall be disclosed in the contract register maintained by the Ministry of Interior. The Parties agreed that the publication of the Agreement through contract register shall be performed by the Hospital, no later than within 5 working days from the signing of the Agreement by the last Party. The proposal of version of the Agreement for publication shall be sent by Principal to the Hospital to the e-mail address xxxxxx in electronic form in machine readable format on the day of signature of the Agreement at the latest and before its publication shall be mutually agreed by the Principal and the Hospital via email.
	* 1. Written Form

Amendments and complements to this Agreement must be made in writing in order to be effective. This also applies to the waiver of the written form requirement.

* + 1. Applicable Law and Legal Venue
1. The Parties agree that the present Agreement shall be governed by the laws of the Czech republic.
2. Principal and Institution agree that all legal disputes between them arising from or in connection with this Agreement or its performance shall be subject to the jurisdiction of the Czech competent courts.
	* 1. Partial Invalidity and Omissions
3. Should any of the provisions of this Agreement be or become invalid or unenforceable, the Parties agree to replace the invalid or unenforceable provisions or the provisions that have become unenforceable with other valid or enforceable provisions that are so close in economic effect to the invalid or unenforceable provisions that it can be assumed that the Parties would also have concluded this Agreement with this provision in place instead of the invalid or unenforceable provisions.
4. If no such provision is to be found, the invalidity or unenforceability of one or more provisions shall not affect the validity of this present Agreement as a whole. This shall not apply if the invalid or unenforceable provisions or the provisions that have become unenforceable are of such significance for the Agreement that it is reasonable to assume that the Parties would not have concluded the Agreement without the invalid or unenforceable provisions. The foregoing shall apply mutatis mutandis in the event of a contractual loophole.
	* 1. Warranty, Liability, Indemnification

Institution shall conduct the study carefully and in compliance with applicable Laws. The contracting Parties are aware of the risk of success associated with the study. Due to the research character, the Institution does not assume any guarantee for the achievement of a specific work result or that the work results can be commercially exploited or are free of third-party intellectual property rights. Insofar as conflicting intellectual property rights become known, Institution shall inform the Principal thereof without delay.

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**Všeobecná fakultní nemocnice v Praze**

**]:**

[Prague], date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [place], date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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*Acknowledged and agreed:*

[place], date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Project Leader

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*Budget Approval:*

[place], date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Resuscitec GmbH**

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(Resuscitec GmbH) xxxxxxxxxxxxxxxxxxxx

**Exhibits**

Exhibit 1 PMCF-Study Plan “CARL-Registry Study“

Exhibit 2 Patient Information

Exhibit 3 Informed Consent Form

Exhibit 4 pCRF-Documentation Logs

Exhibit 5 Medical Devices provided for Conduct of PMCF-Study