The translation provided is for informational purposes only. The tender procedure is conducted in Polish. In the event of any discrepancies or disputes, the binding version of the agreement is the Polish version.

Annex No. 4 to the RFP

AGREEMENT No. ZP/……../2024

concluded in Gdańsk on ..... between:

Medical University of Gdańsk with its registered office in Gdańsk (80-210) at ul. M. Skłodowskiej-Curie 3a, REGON: 000288627, NIP: 584-09-55-985, BDO: 000046822, represented by:

…… – ……

…… – ……

with financial co-signature of mgr. Zbigniew Tymoszyk – Deputy Chancellor for Financial Affairs – Treasurer, hereinafter referred to as the "Purchaser", "GUMed" or "Sponsor",

and

…… with its registered office in …… NIP: …….. REGON: …… entered into the National Court Register in …… on …… under No. ……represented by:

…… – ……

…… – ……

hereinafter referred to as the "Contractor", "CRO"

hereinafter collectively referred to as the "Parties", and individually as the "Party"

As a result of the selection of the offer by the Purchaser in the procurement procedure conducted in the form of an open tender pursuant to Article 132 of the Act of September 11, 2019, Public Procurement Law (consolidated text Journal of Laws of 2023 item 1605, as amended), hereinafter referred to as the PPL, No. procedure GUM2024_____, the following Agreement was concluded:

The service will be provided as part of the project: ***"Effectiveness and safety of metoprolol as adjunctive therapy in preventing the development of cardiomyopathy in patients with Duchenne muscular dystrophy aged 8-17 years. Randomized, double-blind, parallel-group study with placebo in the control group," hereinafter referred to as the "Project."***

Given that:

1) The Ordering party is implementing the Project on the basis of the agreement of June 25, 2020 on co-financing the project, No. 2019/ABM/01/00026, hereinafter referred to as the "ABM agreement," concluded with the Medical Research Agency, hereinafter referred to as "ABM",
2) The Ordering Party intends to entrust the Contractor with comprehensive supervision of the implementation of the clinical trial at the research center in Newcastle and possibly at a maximum of two other interested centers in Great Britain, within the meaning of the applicable regulations governing the conduct of clinical trials,

the Parties have agreed as follows:

§ 1

Subject Matter of the Agreement

1. The Contractor undertakes to operationally manage the clinical trial within the Project (hereinafter: "Trial") at the center/centers in the United Kingdom. Management includes administrative, logistical, and regulatory issues in accordance with the provisions of this Agreement and in accordance with the Contractor's offer dated ..... 2024, constituting Annex No. 1 to the Agreement, hereinafter referred to as the "Services."
2. The subject of the order includes in particular:

A. PERFORMANCE OF ACTIVITIES RELATED TO THE IMPLEMENTATION OF THE NON-COMMERCIAL CLINICAL TRIAL MeDMD cardiomyopathy, INCLUDING IN PARTICULAR:

1) Verification and submission of study documentation through the Integrated Research Application System (IRAS) to obtain approval from the regulatory agency (MHRA) and the opinion of the ethics committee (REC).
2) Organization and conduct, in cooperation with the Purchaser, of the Study in accordance with the Study Protocol at the research center(s), current regulations of the European Medicines Agency regulating the conduct of clinical trials, guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the Helsinki Declaration, and applicable national regulations.
3) Project management, including planning and conducting meetings and teleconferences, preparing a project management plan.
4) Regularly informing the Purchaser about the progress of the study and any problems.
5) Availability for meetings with representatives of the Purchaser to discuss matters related to the subject of the order.
6) Serving as a contact and information point for researchers and members of the research team, administrative staff of centers, laboratory staff, pharmacists, coordinators, etc. Maintaining active communication with all individuals involved in conducting the Study at each of the centers.
7) Preparation of training materials in English for study coordinators at the centers, research teams on GCP principles, and eCRF operation training.
8) Preparation of a Quality Management Plan for the Study.
9) Preparation of a pharmacy procedure manual in English for the Study and information on drug management, including placebo (Pharmacy Manual).
10) Preparation of a Laboratory Manual in English for laboratory diagnosticians.
11) Development of a comprehensive Monitoring Plan in English.
12) Preparation of Study documentation (ISF - Investigator Study File) in accordance with Good Clinical Practice (GCP) principles for the center/centers contracted in the Study.
13) Supervision of eCRF, including ensuring a coordinator for data entry.
14) Exercising control over data quality in the eCRF, support in resolving queries.
15) Collection of laboratory norms, CV of the laboratory manager, and quality certificates (equipment used in the Study).
16) Preparation of Safety Monitoring Plan.
17) Study Monitoring: Conducting on-site initiation, monitoring, and close-out visits.
18) Study Monitoring: Conducting remote monitoring visits.
19) Monitoring the safety profile of patients undergoing diagnostic/therapeutic procedures. Reporting SUSARs through MHRA Gateway and ICSR Submissions.
20) Preparation and submission of annual medicinal product safety reports to the appropriate authority in the UK.

21) Conducting, on behalf of the Sponsor, all pharmacovigilance monitoring activities in accordance with UK regulations.
22) Database cleaning and closure.
23) Supervision of the quality of statistical data in the study and the statistical results obtained.
24) Preparation of sections for the final Clinical Study Report according to ICH E3 (EMA).
25) Submission of the final report from the conducted study to the appropriate authority in the UK.

STAGES OF ORDER IMPLEMENTATION

STAGE I - Preparation of documentation related to the clinical trial:

– Verification of the documentation received from the Sponsor for compliance with regulations.
– Development of missing documents.
– Submission of study documentation via the Integrated Research Application System (IRAS) to obtain regulatory agency (MHRA) approval and ethical committee (REC) opinion.

STAGE II - Supervision of clinical trial implementation and results development:

– Monitoring of clinical trials at specified research sites, including verification to ensure:
• Protection of the rights and well-being of study participants,
• Accurate, complete, and verifiable data collection based on source documents,
• Documentation, reporting, and analysis of data in accordance with study protocols,
• Conducting the clinical trial according to protocols and accepted protocol amendments.
– Conducting all documentation activities of clinical trials in a secure, IT-based data storage system, providing access to data with the ability to verify changes (eCRF).
– Reporting serious adverse events and other significant medical events through MHRA Gateway and ICSR Submissions, as well as to the Ordering Party, in accordance with legal requirements and deadlines.
– Collaboration of CRO with all individuals involved in service delivery.
– Conducting all activities related to the closure of the clinical trial by the Research Center(s) and Investigators conducting these studies in the UK.
– Maintaining full documentation of the studies and transferring it to the Ordering Party upon completion or termination of this Agreement in any other way.
– Documents will be transferred to the Sponsor after the end of the study in a manner allowing for their archiving.

B. Contact with the Sponsor (Ordering Party) and individuals involved on behalf of the Ordering Party in the implementation of the Study:

1) Telephonic and email communication as required by the progress of the order implementation;
2) Regular reporting to the Ordering Party on the progress of the Study and any problems in the form of monthly written reports and weekly video conferences.
3) Contractor's readiness to meet with representatives of the Ordering Party to discuss issues related to the subject of the order. Meetings will mainly take place online (teleconferences).
4) Preparation of meeting reports.

C. Supervision of pharmacotherapy safety within the Study:

Ensuring support of the Qualified Person Responsible for Pharmacovigilance (QPPV) involving all activities related to monitoring the safety of investigational medicinal products in accordance with national and EU regulations, Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP), and detailed EMA guidelines, including in particular:

1) Sponsor and user registration in the EudraVigilance database and updating data as required.

2) Preparation of the Safety Management Plan (SMP).
3) Receiving and recording adverse event reports from investigators, verifying completeness, conducting follow-up for incomplete reports (24 hours/365 days adverse event reporting surveillance).
4) Evaluation of received reports for expectedness, causality with the investigational product, and severity of the adverse event.
5) Timely submission to URPL, Ethics Committee, investigators in the Study, and inputting and updating in EudraVigilance database (clinical trials module, MedDRA coding) of reports covering suspected unexpected serious adverse reactions (SUSARs).
6) Collection and reporting to relevant authorities of serious adverse events not meeting the SUSAR definition.
7) Continuous benefit-risk assessment in the Study including ongoing adverse event analysis.
8) Ongoing informing of the Sponsor about all significant aspects of the Study, particularly those affecting the safety of clinical trial participants and data quality.
9) Preparation and timely submission to URPL and Ethics Committee of annual safety reports in DSUR format (Development Safety Update Report) and any safety updates. Preparation and distribution of DILs/IND/PSRI.
10) Providing safety data for the Study Final Report.
11) Preparation of Narratives.
12) Ongoing informing of the Sponsor about all legislative changes affecting the Study.

3. The Contractor shall perform its obligations with due diligence, in accordance with applicable law, in particular:

3.1 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, concerning the harmonization of legal, regulatory, and administrative provisions of the Member States relating to the implementation of the principles of good clinical practice in the conduct of clinical trials of medicinal products for human use;

3.2 Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorizing the manufacturing and importation of such products;

3.3 Act of 9 March 2023 on clinical trials of medicinal products for human use, along with executive acts regulating the issue of clinical trials (i.e., Journal of Laws of 2024, item 605);

3.4 Act of 6 September 2001 Pharmaceutical Law (i.e., Journal of Laws of 2022, item 2301, as amended);

3.5 Act of 5 December 1996 on the professions of physician and dentist (i.e., Journal of Laws of 2023, item 1516, as amended);

3.6 Regulation of the Minister of Health of 3 August 2021 on Good Laboratory Practice and conducting studies in accordance with the principles of Good Laboratory Practice (Journal of Laws of 2021, item 1422, as amended);

3.7 Regulation of the Minister of Health of 2 May 2012 on Good Clinical Practice (Journal of Laws of 2012, item 489, as amended);

3.8 Regulation of the Minister of Health of 17 October 2018 on templates of documents submitted in connection with the clinical trial of a medicinal product and on the amount and method of payment of fees for initiating a clinical trial (Journal of Laws of 2018, item 1994);

3.9 Always in accordance with the current version of the Declaration of Helsinki of the World Medical Association, as well as with GCP principles.

4. The Contractor may subcontract (any part of) the Services only after obtaining prior written consent from the Sponsor.

5. The Contractor confirms that it is authorized to provide Services in the country of registration (where Services would need to be performed by the CRO). Upon the Sponsor's first request, the CRO will promptly issue valid certificates in this regard. In appropriate cases, the CRO will take all necessary actions to continue providing Services and update these certificates.

6. In order to properly execute the order, the Ordering Party authorizes the Contractor, among other things, to:

- sign relevant documents related to the application and respond to inquiries regarding the application,

- submit changes and respond to inquiries regarding changes,

and the Ordering Party will develop a Communication Plan, which will be provided to the Contractor after the conclusion of this Agreement.

§ 2

Contractor's Obligations

1. The Contractor's obligations include in particular:

   1) appointment of individuals responsible for the implementation of the Agreement;

      The list of individuals responsible for the implementation of the Agreement on the Contractor's side will constitute Annex No. 4 to the Agreement. The subject of the Agreement will be executed by individuals listed in Annex No. 4 to the Agreement;

   2) acting on behalf and for the account of the Ordering Party, with an application to the Ethics Committee, the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products, or other authorities, if necessary, and also at the request of the Ordering Party, concluding an agreement with research center/research centers.
   3) analysis of documents sent by GUMed, including the development and provision of procedures and instructions to investigators regarding the conduct of clinical trials at the research center, including instructions for using the IT system.
   4) conducting all documentation activities of the Study in a secure, IT-based data storage system, ensuring access to data with the ability to verify introduced changes.
   5) making payments for the performance of the Study to the research centers referred to in the first sentence of § 1 para. 2), while observing the deadlines specified in the Act of 8 March 2013 on counteracting excessive delays in commercial transactions (Journal of Laws of 2021, item 424);
   6) preparation of quarterly periodic reports and final study reports.
   7) submission, in a manner and within the deadlines specified by law, of reports on serious adverse events and other significant medical events to the relevant ethics committees and competent authorities, offices, and organizations responsible for the registration of medicinal products or supervision, audits, or inspections of clinical trials.
   8) informing the Ordering Party of all actions taken by the Contractor that may affect the timely execution of the order.
   9) cooperation with GUMed.

2. The Ordering Party may consent to a change of individuals referred to in para. 1 point 1), provided that the person indicated as a substitute has knowledge and experience at least equal to the person listed to meet the conditions for participation in the proceedings that resulted in the conclusion of

this Agreement. The change of person will occur upon the Contractor's written request with justification for the change. The Ordering Party will grant or refuse consent to the change in writing. This change does not require an annex to the Agreement.

§ 3

Obligations of the Ordering Party

1. The obligations of the Ordering Party include in particular:

1) appointment of individuals responsible for the implementation of the Agreement:

a) Project Manager from the GUMed side.

b) Investigators responsible for the Study.

c) Nurses, in agreement with the research center.

The list of individuals responsible for the implementation of the Agreement on the part of the Ordering Party will constitute Annex No. 5 to the Agreement.

2) participation in all activities related to the development of necessary documentation.

3) arranging mandatory insurance for the Sponsor, investigators, and other individuals comprising research teams against civil liability for damages caused in connection with conducting clinical trials, in accordance with applicable regulations governing the conduct of clinical trials.

4) making timely payments for services provided.

2. Changes to the individuals referred to in para. 1 point 1) are permitted, provided that the Contractor is notified of the change in writing. This change does not require an annex to the Agreement.

§ 4

Preparation and Changes to Study Documentation

1. The Contractor will prepare the documentation used in the Study.
2. The documents prepared by the Contractor for use in the Study, before their use or submission to the appropriate ethics committee or relevant authority, organization, or institution responsible for the registration of medicinal products or supervision, audit, or inspection of clinical trials, require approval by the Project Manager from the GUMed side.
3. In the case of making changes to the documents referred to in para. 1, the provisions of para. 2 apply.
4. The Ordering Party reserves the right to commission an independent entity with the appropriate knowledge to audit the documentation prepared by the Contractor.
5. In the event of discrepancies in the documentation with the standards applicable in clinical trials identified by the auditing entity, the Ordering Party will instruct the Contractor to rectify the discrepancies. In such a case, the costs of the audit shall be borne by the Contractor.
6. The consequences of delays in the performance of the Agreement resulting from the need to rectify discrepancies shall be borne by the Contractor.

§ 5

Agreement with the Research Center in Newcastle

1. Within 14 days from the date of concluding the Agreement, the Contractor, based on the existing draft agreement, will establish detailed terms for the final version of the agreement and provide them to the Project Manager from the GUMed side. The final version of the agreement will comply with the relevant legal regulations governing the conduct of clinical trials and will be concluded between the Ordering Party, acting as the Sponsor of the clinical trials, and the research center appropriate for conducting the trials.
2. The draft agreement referred to in para. 2 must comply with legal regulations, the provisions of this Agreement, and the agreement with ABM.

§ 6

Documentation, Audits, and Inspections

1. The Contractor shall promptly provide the Ordering Party with copies of all documents prepared, sent, submitted, or received in the performance of the obligations referred to in § 1, in particular:

   1)applications submitted to the relevant ethics committee and appropriate authorities, offices, and organizations responsible for the registration of medicinal products or supervision, audit, or inspection of clinical trials;

   2)decisions, opinions, and other documents received from the relevant ethics committees and appropriate authorities, offices, and organizations responsible for the registration of medicinal products or supervision, audit, or inspection of clinical trials;

   3)documents referred to in § 1 para. 2.

2. Upon justified request of the Ordering Party, the Contractor shall, at any time, provide the Ordering Party with information on the progress of the order's implementation. In particular, the Ordering Party may request the Contractor to prepare a report on the activities performed. In such a case, the Contractor shall submit the relevant report within 14 days from the date of the request.

3. During the term of this Agreement, the Contractor undertakes to allow the appropriate ethics committee and relevant national, foreign, and international authorities and organizations responsible for the registration of medicinal products or supervision, audit, or inspection of clinical trials: to conduct audits, inspections, and controls of the trials, as well as to access documents related to the conduct of the trials and to monitor and audit the actions of investigators and members of research teams involved in the trials (including inspections and audits of premises, procedures used in the trials by investigators and members of research teams, as well as equipment, methods of data documentation, and storage of documentation) and to obtain all information regarding the conducted trials, both by national, foreign, and international authorities or organizations responsible for the registration of medicinal products or supervision, audit, or inspection of clinical trials.

4. The Contractor shall promptly notify the Ordering Party if the relevant ethics committee or appropriate national, foreign, or international authorities or organizations responsible for the registration of medicinal products or supervision, audit, or inspection of clinical trials inform the Contractor of a planned inspection or commence an inspection of the Contractor or any research center or ethics committee associated with any of the trials without prior notice.

5. Upon request of the Ordering Party, the Contractor undertakes to promptly take all reasonable and feasible actions to rectify any irregularities identified during the conducted inspection or audit.

6. Upon completion of the performance of this Agreement, the Contractor shall provide the Ordering Party with the original complete documentation of the trials, including originals of any decisions and resolutions issued by the relevant ethics committees or appropriate national, foreign, or international authorities or organizations.

§ 7

Deadlines for the Implementation of the Agreement

1. The subject of the order will be completed within a maximum period of 76 months from the date of conclusion of the agreement, including the implementation of Stage No. 1 of the order within 60 calendar days from the date of conclusion of the Agreement, subject to paragraph 2.

2. A necessary condition for the commencement and continuation of the agreement (Stage No. 2 of the order) is the completion of Stage 1 of the order.

3. The Ordering Party allows for an extension of the term of service performance (Stage No. 2 of the order). The length of the extended term will depend on the extension of the Project implementation term in accordance with the annex to the agreement with ABM.

4. The agreement shall be terminated in the event of project closure or failure to obtain consent to commence a clinical trial issued by the relevant body in Great Britain.

5. The detailed cost estimate with a schedule constituting Annex No. 2 to the agreement will specify the dates in which the Contractor, after partial acceptance (stages, tasks and activities), will be entitled to issue a VAT invoice including part of the remuneration specified in § 10.

§ 8

The Ordering Party's Commitment to Provide Contract Content

1. Within 7 days from the conclusion of this Agreement, the Ordering Party shall provide the Contractor with copies of contracts with ABM concerning the Project.

2. The Ordering Party undertakes, during the term of the Agreement, to inform the Contractor of planned changes to the contracts referred to in para. 1 and to provide the Contractor with copies of any changes to these contracts or additional agreements concluded thereto, which may affect the Contractor's obligations under this Agreement.

3. The Ordering Party may remove from the documents provided to the Contractor under para. 1 and para. 2 provisions that do not affect the Contractor's obligations under this Agreement.

4. The Ordering Party cannot invoke provisions of the contracts referred to in para. 1 that have not been disclosed to the Contractor in accordance with this paragraph when verifying the compliance of the actions performed by the Contractor under this Agreement with the provisions of the contracts referred to in para. 1.

§ 9

Acceptance of the completed work

1. Acceptance of the subject of the Agreement will take place in parts, while observing the deadlines specified in Annex No. 2, and for settlement purposes, completed tasks and activities specified in Annex No. 2, for which no reservations have been made (partial acceptances), subject to para. 2.

2. Partial acceptance of the subject of the Agreement after concluding the agreement with the center in Newcastle will take place no more than once a month and will include tasks or activities completed in the given settlement period.

3. The Contractor shall notify the Ordering Party of the readiness for partial acceptance of the subject of the Agreement in writing/electronically. Partial acceptances shall be made within 7 days from the date of submission of the required acceptance documents to the Ordering Party. The Partial Acceptance Protocol Template constitutes Annex No. 6 to the Agreement.

4. If defects are found during the acceptance procedure, the Contractor is obliged to rectify them within the deadline specified by the Ordering Party. After their rectification, acceptance will be conducted in accordance with para. 3, 4, and 5.

5. Acceptance of parts of the subject of the Agreement shall be deemed to have occurred at the moment of signing the Partial Acceptance Protocol by the representatives of the Parties:

   1) on behalf of GUMed:

   [Name], tel. [phone number], email: [email] or a person authorized by them.

   2) on behalf of the Contractor:

   [Name], tel. [phone number], email: [email] or a person authorized by them.

6. The basis for settlement of payments for the performance of the entire subject of the Agreement will be the Final Acceptance Protocol, drawn up according to the template constituting Annex No. 7 to the Agreement, confirming the completion of the subject of the Agreement and the transfer of full documentation to the Ordering Party. The provisions of para. 3-5 shall apply mutatis mutandis to the final acceptance.

§ 10

Remuneration

1. For the performance of the subject of the Agreement, the Ordering Party shall pay the Contractor the remuneration specified in the content of the offer and in the detailed cost estimate, constituting Annex No. 1 to the Agreement and Annex No. 2 to the Agreement, respectively, up to the total amount of PLN ..... gross (in words: .....), including VAT ..... % in the amount of PLN ..... 2. The remuneration specified in paragraph 1 shall cover all costs and expenses of the Contractor related to the performance of the subject of the Agreement, as well as the ownership of copies and media on which the works referred to in § 12 have been recorded. 3. The above-mentioned gross remuneration may not be increased during the performance of the Agreement, subject to § 18.

§ 11

Payment Terms

1. The Parties to the Agreement agree that the settlement of the agreed remuneration, as specified in § 10 para. 1, regarding partial acceptances of the subject matter of the Agreement, will be conducted according to the terms specified in § 9 para. If the amount invoiced on the VAT invoice exceeds the agreed price, the Ordering Party will make payment only up to the agreed price, and the Contractor undertakes to promptly issue a correctiveng Party's side.
2. When issuing partial invoices, the Contractor is obliged to include references to specific Partial Acceptance Protocols.

3. Final settlement - payment of the last part of the remuneration resulting from the provisions of the Agreement - will take place after signing the Final Acceptance Protocol. The basis for issuing the final invoice by the Contractor is the Final Acceptance Protocol without reservations.
4. The amount of partial invoices cannot exceed 90% of the remuneration referred to in § 10 para. 1. The remaining part of the remuneration will be settled by the final invoice after the Project Manager on the GUMed side signs the Final Acceptance Protocol without reservations.
5. The Ordering Party shall make payment for the amounts due from VAT invoices issued by the Contractor within 30 days from the date of submission of a properly issued invoice along with the relevant acceptance protocols as referred to in § 9.
6. The Ordering Party allows the submission of VAT invoices in the form of:
   a) paper, with the original invoice to be submitted to the GUMed Office, ul. M. Skłodowskiej -Curie 3a, 80-210 Gdańsk;
   b) a pdf file, sent to the address: faktury@gumed.edu.pl and dnbk@gumed.edu.pl, with the invoice number, procedure number, and the name of the invoice issuer included in the message title;
   c) a structured electronic document submitted via the Electronic Invoicing Platform, hereinafter referred to as PEF, in accordance with the Act on Electronic Invoicing in Public Procurement, Concessions for Construction Works or Services, and Public-Private Partnership of November 9, 2018 (consolidated text Dz.U. 2020 item 1666, as amended).
7. Payment will be made to the Contractor's bank account no. .....;
8. The date of payment shall be deemed to be the date of debit to the Ordering Party's bank account.
9. The Parties agree that the Ordering Party is responsible only for its obligations arising from this Agreement.
10. The Parties agree that payment will be made only to the bank account number listed in the list referred to in Article 96b of the Act of March 11, 2004, on Goods and Services Tax (consolidated text Dz.U. of 2024, item 361, as amended), hereinafter referred to as the "List". The Contractor is obliged to notify the Ordering Party of the removal of the bank account from the List immediately, but no later than three business days before the invoice payment deadline. The notification should be sent to the email address: faktury@gumed.edu.pl and dnbk@gumed.edu.pl The Ordering Party reserves the right to withhold payment of the invoice until the bank account number is changed to one listed in the List, without the right to demand interest for delay in commercial transactions from the Contractor, who agrees to this, subject to para. 11.
11. The provisions of para. 10 apply only to Contractors who are active VAT taxpayers in Poland.
12. The structured electronic invoice (in case this document form is chosen) must contain data required by the provisions of the Act of March 11, 2004, on Goods and Services Tax (consolidated text Dz.U. of 2024, item 361, as amended), and at least the following information:
a) information about the payment recipient;
b) indication of the public procurement contract.
13. The Ordering Party informs that the PEPPOL identifier/PEF address of the Ordering Party, enabling the submission of a structured electronic invoice, is: VAT ID 584-09-55-985.
14. In case of delayed payment, the Contractor is entitled to statutory interest for delay in commercial transactions, as referred to in Article 4(3) of the Act of March 8, 2013, on counteracting excessive delays in commercial transactions (consolidated text Dz.U. of 2023, item 1790, as amended).
15. The Ordering Party's commitment concerns the receivables specified in the Agreement. If the amount invoiced on the VAT invoice exceeds the agreed price, the Ordering Party will make payment only up to the agreed price, and the Contractor undertakes to promptly issue a corrective invoice.

§ 12

Intellectual Property Rights

1. Under this Agreement, as part of the contractual remuneration, the Ordering Party acquires exclusive ownership of all intellectual property rights arising from its execution, including rights to research results, databases, and generated documentation. The rights mentioned in this paragraph include, in particular, copyright and related rights, industrial property rights, patents, protective rights, rights from the registration of industrial designs, know-how, utility models. In the course of executing this Agreement, the Contractor shall not acquire any rights to the aforementioned results. All proprietary copyright rights to research results and other works, as well as databases, arising from the execution

of this Agreement or agreements concluded within its framework, together with the right to exclusively authorize the exercise of dependent copyright, transfer to the Ordering Party upon their establishment. The proprietary copyright rights, together with the right to exclusively authorize the exercise of dependent copyright, transfer to the Ordering Party in full, without territorial or temporal limitations, in all fields of exploitation, including: in terms of fixation and reproduction - production of copies of the work by any technique, including printing, reprographic, magnetic recording, and digital techniques, as well as introducing the work into a computer memory; concerning the original work or copies on which the work is fixed - entering into circulation, lending, leasing, or renting the original or copies; in terms of dissemination of the work in another way - public performance, exhibition, display, reproduction, broadcasting, and retransmission by wire or wireless means via terrestrial station or satellite, as well as public provision of access to the work in such a way that anyone can access it at a time and place of their choosing, including through provision via the Internet.

2. Upon the transfer of proprietary copyright to works referred to in paragraph 1, the Ordering Party acquires the right to use and dispose of the developments of these works (dependent rights), as well as the right to grant further permissions to use and dispose of these developments.
3. The Contractor grants the Ordering Party permission to make any changes and adaptations to the works referred to in paragraph 1, either personally or through third parties, including their use in whole or in part and their combination with other works.
4. The Contractor ensures that individuals entitled under personal copyright rights to the works will not exercise such rights against the Ordering Party, its successors in title, and licensees.
5. The Contractor is obliged to include appropriate provisions guaranteeing the implementation of the principles indicated in this paragraph in all agreements concluded in the performance of this Agreement. If, as a result of the Contractor's action or inaction, the Ordering Party does not obtain exclusive rights as described in this paragraph, or if the rights obtained by it are encumbered or limited by the rights of third parties, the Contractor shall be liable for any resulting damage on general terms.
6. To eliminate any doubts, the Parties declare that the remuneration received by the Contractor under this Agreement includes the transfer of proprietary copyright in all fields of exploitation as referred to in paragraph 1.

§ 13

Confidentiality

1. The Contractor undertakes to keep in strict confidence all information concerning the Project, conducted as part of the Research Project and the Ordering Party, which it obtains as part of the performance of this Agreement.
2. The above obligation does not apply to information that has been made public in accordance with the law.
3. In the event of disclosure or use by the Contractor of the information referred to in paragraph 1 in a manner inconsistent with this Agreement, the Ordering Party may use all available legal remedies, and in particular the possibility of holding the Contractor liable, as referred to in the Act of 16 April 1993 on combating unfair competition (consolidated text: Journal of Laws of 2022, item 1233).
4. Due to the fact that during the performance of the subject of the Agreement, the Contractor will process personal data on behalf of the Ordering Party, the Parties will conclude an agreement on entrusting the processing of personal data, in accordance with the template specified in Annex No. 8 to the Agreement.
5. In accordance with Art. 13 sec. 1 and 2 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ EU L 119 of 04.05.2016, p. 1), hereinafter referred to as "GDPR", I inform you that:
   1) The administrator of your personal data is the Medical University of Gdańsk, ul. M. Skłodowskiej-Curie 3a, 80-210 Gdańsk, contact with the Personal Data Protection Officer is possible at the following e-mail address: iod@gumed.edu.pl

2) Your personal data will be processed on the basis of:
- art. 6 sec. 1 letter c GDPR in connection with the Act of 11 September 2019 - Public Procurement Law (consolidated text: Journal of Laws of 2023, item 1605, as amended), hereinafter referred to as "PZP", Regulation of the Minister of Development, Labour and Technology of 23 December 2020 on the subjective means of evidence and other documents or declarations that the ordering party may request from the contractor in order to conduct and resolve the public procurement procedure (Journal of Laws of 2020, item 2415),
- art. 6 sec. 1 letter b GDPR in order to conclude a public procurement contract with the selected contractor and perform this contract.
3) The recipients of your personal data will be persons or entities to whom the documentation of the procedure will be made available on the basis of art. 18 and art. 74 PZP and public authorities or other entities authorized under the law or entities providing technical, IT and advisory services, including legal and consulting services, document archiving companies, postal operator.
4) Your personal data will be stored, in accordance with art. 78 sec. 1 and sec. 4 PZP for a period of 4 years from the date of completion of the procurement procedure, and if the duration of the contract exceeds 4 years, the storage period covers the entire duration of the public procurement contract;
5) Providing data is necessary to participate in the procedure. The obligation to provide your personal data directly concerning you is a requirement specified in the provisions of the PZP and implementing regulations related to participation in the public procurement procedure; the consequences of failure to provide certain data result from the PZP Act.
6) In relation to your personal data, decisions will not be made in an automated manner, in accordance with art. 22 of the GDPR;
7) You have:
- pursuant to art. 15 GDPR the right to access your personal data;
- based on art. 16 GDPR the right to rectify your personal data
- based on art. 18 GDPR the right to request the controller to restrict the processing of your personal data, subject to the cases referred to in art. 18 sec. 2 GDPR;
- the right to lodge a complaint with the President of the Personal Data Protection Office if you consider that the processing of your personal data violates the provisions of the GDPR;
8) You are not entitled to:
- in connection with art. 17 sec. 3 letters b, d or e GDPR the right to delete your personal data;
- the right to transfer your personal data, referred to in art. 20 GDPR;
- based on art. 21 GDPR the right to object to the processing of your personal data, as the legal basis for the processing of your personal data is art. 6 sec. 1 letter c GDPR.

6. In accordance with art. 75 PZP in the event that a person exercises the right referred to in art. 15 sec. 1-3 of the GDPR, the ordering party may request the person making the request to provide additional information aimed at specifying the name or date of the completed contract award procedure. In accordance with art. 19 sec. 2 of the PZP, the exercise by the data subject of the right to rectify or supplement personal data referred to in art. 16 of the GDPR may not result in a change in the outcome of the public procurement procedure or a change in the provisions of the public procurement contract to the extent inconsistent with the Act. In accordance with art. 19

§ 14

Significant Amendment to the Agreement

1. The Ordering Party, in accordance with Article 455(1)(1) of the Public Procurement Law, foresees the possibility of changes to the Agreement in the following cases:

1) Changes to the timeframes defining the Research framework;
2) Changes to the number of disease units - participants in the Study;
3) Significant change to the content of the agreement concluded between the Ordering Party and ABM or any other legal event affecting the scope of the Ordering Party's obligations, including extending the Project implementation period;
4) Changes to applicable law, in the scope of the rules for conducting clinical trials of medicinal products or in any other area where obligations related to conducting clinical trials or preparing registration documentation will be modified;
5) The occurrence of force majeure;

6) Suspension of the implementation of the subject matter of the Agreement by the Ordering Party (including due to ABM's decision to suspend funding), not resulting from the fault of the Contractor.

2. The changes referred to in paragraph 1 may concern:

1) Increasing or decreasing the Contractor's remuneration due to an increase or decrease in the amount of work necessary to perform the Agreement, especially in the case of changes in the number of disease units covered by the Study, provided that the minimum remuneration will be at least 30% of the remuneration specified in § 10(1) of the Agreement;
2) Shifting the deadlines for the implementation of individual obligations comprising the subject matter of the Agreement.

3. The condition for implementing changes referred to in paragraph 1, if they entail postponing the expected completion date of a given task or activity or increasing the costs of performing one or more tasks or activities or necessitate any changes to the agreement concluded by the Ordering Party with ABM, is the prior consent of ABM or another authorized body.

§ 15

Termination of the Agreement

1. The Ordering Party, regardless of the statutory right to terminate the Agreement, has the contractual right to terminate the Agreement in whole or in part in the following cases:

1) If preliminary results obtained during the implementation of clinical trials significantly indicate that continuing the trials will not confirm the safety or efficacy of the medicinal product under study, within the scope of the agreement between the Ordering Party and ABM;
2) If, for reasons not attributable to the Ordering Party, there is a delay in the implementation of the Study in relation to the deadlines specified in Annex No. 2, exceeding 30 days, making it impossible to perform the agreement with ABM, concluded between the Ordering Party and ABM;
3) Identification by the Ordering Party of a physical or legal defect in the subject matter of the Agreement, preventing the performance of the agreement with ABM, concluded between the Ordering Party and ABM;
4) Termination of the agreement with ABM, which is the source of funding for the Study, or suspension of funding by ABM under that agreement;
5) Unjustified interruption by the Contractor of the performance of the subject matter of the Agreement and ineffective expiry of the deadline set by the Ordering Party for the resumption of its performance;
6) Faulty execution by the Contractor of the subject matter of the Agreement or in a manner contrary to the Agreement, or the application of solutions conflicting with the assumptions provided by the Ordering Party and agreed upon with them, after the ineffective expiry of the deadline set by the Ordering Party for the Contractor to change the method of performing the subject matter of the Agreement;
7) Improper performance of obligations arising from the agreement on entrusting the processing of personal data, as referred to in § 13(4), after the ineffective expiry of the deadline set by the Ordering Party for the Contractor to change the method of performing this agreement;

8) In the event of the Sponsor's decision to terminate the Study prematurely.

2. The right to terminate the Agreement, as referred to in paragraphs 1(1)-(5) and (9), may be exercised by the Ordering Party within 60 days from the date of learning about the reason justifying the termination of the Agreement, and in the case specified in paragraph 1(6)-(8), within 60 days from the ineffective expiry of the deadline set in the summons.

3. Therefore, the parties agree that in the event referred to in the sentences above, intellectual property rights, as referred to in § 12, shall transfer to the Ordering Party in full scope specifiedrdering Party may terminate the Agreement within 30 days from learning about these circumstances. In such a

case, the Contractor may demand only the remuneration due for the performance of part of the agreement.

4. In the event of termination of the Agreement, the Contractor is obliged to immediately suspend work and return documents received from the Ordering Party, unless the Ordering Party releases the Contractor from this obligation.

5. The statement of termination of the Agreement must be made to the other party in writing under pain of invalidity. The statement of termination of the Agreement must include justification.

6. If the Ordering Party terminates the Agreement in part, the Contractor has the right to retain the remuneration received from the Ordering Party for the part received before the date of termination of the Agreement, while the Ordering Party has the right to retain and use the documentation and the remaining scope of work received, which it received from the Contractor and accepted by acceptance protocols. Therefore, the parties agree that in the event referred to in the sentences above, intellectual property rights, as referred to in § 12, shall transfer to the Ordering Party in full scope specified in § 12.

§ 16

Contractual Penalties

1. In the event of non-performance or improper performance of the Agreement, the Ordering Party has the right to impose the following contractual penalties:
   1) in the amount of 0.1% of the remuneration specified in Annex No. 2 for the performance of a given task or activity - for delay in the implementation of individual tasks or activities specified in Annex No. 2, for each day of delay;
   2) in the amount of 10% of the gross remuneration specified in § 10 para. 1 of the Agreement - in the event of termination of the Agreement due to reasons attributable to the Contractor.

2. The total maximum amount of contractual penalties imposed under this Agreement may not exceed 20% of the gross remuneration specified in § 10 para. 1 of the Agreement.

3. The Contractor agrees to offset the amount of contractual penalties directly upon payment of the VAT invoice, after prior notice to the Contractor to pay these penalties within a specified period, not shorter than 7 days, and after the ineffective expiry of this period.

4. The Ordering Party is entitled to seek additional compensation exceeding the amount of the reserved contractual penalty on general principles. This applies in particular in cases where, as a result of delays in the performance of the Agreement or failure by the Contractor to comply with the provisions of the Agreement, the Ordering Party incurred damage related to the suspension or necessity of refunding part or all of the funding granted by ABM.

§ 17

Conflicts of Interest

1. The Contractor declares and guarantees that there are no contractual or other obstacles hindering their engagement and performance of this Agreement.
2. During the term of the Agreement, the Contractor will continuously inform the Sponsor about any other factual or potential undertakings, business activities, or interests that could lead to a conflict of interest with the Sponsor or otherwise disrupt the proper execution of this Agreement. The Sponsor will then have the option to withdraw from the Agreement in whole or in part without the need to pay any amounts, except for overdue invoice payments. In such a case, the provisions of § 15 para. 2, 4, 5, and 6 apply.

§ 18

Change of Agreement Regarding Contractor's Remuneration

1. The Parties undertake to amend the amount of remuneration due to the Contractor, as referred to in § 10 para. 1, by written annex, each time in the event of one of the following circumstances:
    1) changes in the value-added tax rate,
    2) changes in the minimum wage or minimum hourly rate established on the basis of the Act of October 10, 2002, on the minimum wage,
    3) changes in the rules of social security coverage or health insurance or the amount of the social security or health insurance contribution rate,
    4) changes in the rules of accumulation and amount of payments to employee capital plans, as referred to in the Act of October 4, 2018, on employee capital plans,
    - on the terms and in the manner specified in paras. 2 - 10, if these changes will affect the costs of performing the Agreement by the Contractor.
2. The change in the amount of remuneration due to the Contractor in the event of the circumstance referred to in para. 1 point 1 shall apply exclusively to the part of the Agreement's subject matter completed in accordance with the terms set forth in the Agreement, after the effective date of the provisions changing the value-added tax rate, and only to the part of the Agreement's subject matter to which the change in the value-added tax rate applies.
3. In the event of a change referred to in para. 1 point 1, the net remuneration value will remain unchanged, and the gross remuneration value will be calculated based on the new provisions.
4. The change in the amount of remuneration in the event of the circumstances referred to in para. 1 points 2-4 shall cover only the part of the remuneration due to the Contractor in relation to which there has been a change in the costs of performing the Agreement by the Contractor due to the entry into force of provisions respectively changing the minimum wage or making changes in the scope of social security or health insurance coverage or in the amount of the social security or health insurance contribution rate or making changes in the rules of accumulation and amount of payments to employee capital plans.
5. In the event of a change referred to in para. 1 point 2, the Contractor's remuneration will change by an amount corresponding to the increase in the Contractor's costs associated with increasing the wages of employees providing the Services to the level of the currently applicable minimum wage, taking into account all public law burdens from the amount of the minimum wage increase. The amount corresponding to the increase in the Contractor's costs will apply exclusively to the part of the remuneration for employees providing the Services mentioned above, corresponding to the scope in which they perform tasks directly related to the implementation of the subject matter of the Agreement.
6. In the event of a change referred to in para. 1 points 3 and 4, the Contractor's remuneration will change by an amount corresponding to the change in the Contractor's costs incurred in paying remuneration to employees providing the Services. The amount corresponding to the change in the Contractor's costs will apply exclusively to the part of the remuneration for employees providing the Services mentioned above, corresponding to the scope in which they perform tasks directly related to the implementation of the subject matter of the Agreement.
7. The change in the amount of remuneration due to the Contractor in the event of the circumstance referred to in para. 1 point 4 shall apply exclusively to the part of the Agreement's subject matter completed in accordance with the terms set forth in the Agreement, after the effective date of the provisions changing the rules of accumulation and amount of payments to employee capital plans.
8. In order to conclude the annex referred to in para. 1, each of the Parties may apply to the other Party with a request to change the amount of remuneration due to the Contractor, along with a justification containing, in particular, a detailed calculation of the total amount by which the Contractor's remuneration should change, and indicating the date from which the change in the costs of performing the Agreement by the Contractor justifying the change in the amount of remuneration due to the Contractor occurred or will occur.
9. In the case of changes referred to in para. 1 points 2-4, if the request is made by the Contractor, they are obliged to attach to the request documents showing the extent to which these changes affect the costs of performing the Agreement, in particular:
    1) a written list of salaries (both before and after the change) of employees providing the Services, along with an indication of the scope (part-time) in which they perform tasks directly related to the implementation of the subject matter of the Agreement and the part of the remuneration corresponding to this scope - in the case of a change referred to in para. 1 point 2, or

2) a written list of salaries (both before and after the change) of employees providing the Services, along with the amounts of contributions paid to the Social Security Institution/Agricultural Social Insurance Fund in the part financed by the Contractor, specifying the scope (part-time) in which they perform tasks directly related to the implementation of the subject matter of the Agreement and the part of the remuneration corresponding to this scope - in the case of a change referred to in para. 1 point 3.
3) a written list of salaries (both before and after the change) of employees providing the Services, along with an indication of the scope (part-time) in which they perform tasks directly related to the implementation of the subject matter of the Agreement and the part of the remuneration corresponding to this scope - in the case of a change referred to in para. 1 point 4.

10. In the case of a change referred to in para. 1 point 3, if the request is made by the Ordering Party, they are entitled to require the Contractor to submit within a specified period, not shorter than 14 days, documents showing the extent to which this change affects the costs of performing the Agreement, including a written list of salaries as referred to in para. 9 point 2.

11. Regardless of the provisions of the preceding paragraphs, pursuant to Article 439 of the Public Procurement Law, in the event of a change in the price of materials or costs related to the implementation of the subject matter of the Agreement compared to the price of materials or costs used as the basis for determining the Contractor's remuneration included in the offer, each time by more than 3%, a change in the Contractor's remuneration is allowed, under the following conditions:

1) The change in the Contractor's remuneration may take effect no earlier than after every subsequent 12 months of the validity of this Agreement, counting from the date of its conclusion.
2) The change in the Contractor's remuneration involves its increase (in the event of an increase in the prices of materials or costs associated with the implementation of the subject matter of the Agreement) or decrease (in the event of a decrease in the prices of materials or costs) by the average annual index of consumer goods and services prices, announced in the communication of the President of the Central Statistical Office for the previous year (on a year-to-year basis).
3) The party applying for a change in the Contractor's remuneration, as mentioned in point 2, is obliged to document the change in the prices of materials or costs and demonstrate the impact of this change on the cost of performing the subject matter of the Agreement.
4) The maximum value of the change in the Contractor's remuneration permitted by the Ordering Party as a result of the application of provisions regarding the principles of introducing changes in the amount of remuneration is 5% of the remuneration included in the Contractor's offer.

12. The Contractor, whose remuneration has been changed in accordance with §11, is obligated to adjust the remuneration due to the subcontractor, with whom a contract has been concluded in connection with the Agreement, to reflect the changes in material prices or costs related to the subcontractor's obligations, if the subject of this contract is services, and its duration exceeds 12 months.

13. In any case of non-payment or delayed payment of the remuneration due to the subcontractor resulting from the change in the amount of remuneration as referred to in §12, the Ordering Party shall charge the Contractor with a contractual penalty in the amount of 2,000.00 PLN.

14. Within 14 days from the date of receiving the application mentioned in §8, or the application mentioned in §11 point 3, the Party receiving the application shall provide the other Party with information on the scope of approval of the application and indicate the amount by which the remuneration due to the Contractor should be changed, or provide information on the non-approval of the application along with justification.

15. In the event of receiving information from the Party about the non-approval of the application or partial approval of the application, this Party may reapply with the application mentioned in §8, or with the application mentioned in §11 point 3. In such a case, the provisions of §8 - 10 or the provisions of §11 - 13 shall apply accordingly.

16. The annex shall be concluded no later than 14 days from the date of approval of the application to change the amount of remuneration due to the Contractor.

§ 19

Verification of the Employment Obligation for Employees

1. The Contractor declares that during the period from the date of contract conclusion to the date of its completion, the persons performing activities related to the implementation of the contract, i.e., tasks directly related to the execution of the subject of the contract (supervision over the comprehensive implementation of a clinical trial (CRO) in the United Kingdom), will be employed by the Contractor or subcontractor on the basis of an employment contract as defined by the provisions of the Act of June 26, 1974 - Labor Code (consolidated text: Journal of Laws of 2023, item 1465).
2. The Contractor is obliged to document the fact of meeting the requirements referred to in paragraph 1 above, to the extent that allows verification that the activities specified in paragraph 1 are performed by persons employed on the basis of an employment contract, including indicating the number of these persons, the type of employment contract, and the employment status as well as the entity employing these persons.
3. During the implementation of the contract, the Ordering Party is entitled to perform control activities towards the Contractor regarding the fulfillment of the requirements by the Contractor or subcontractor, as referred to in paragraph 1. The Ordering Party is particularly entitled to:
    1) Request statements and documents confirming the fulfillment of the aforementioned requirements and assess them, in particular, statements of employed workers, statements from the Contractor or subcontractors about the employment of workers based on an employment contract, copies of employment contracts of employed workers certified as true copies, other documents containing information, including personal data, necessary to verify employment based on employment contracts, especially the first and last names of employed workers, the date of conclusion of employment contracts, the type of employment contracts, and the scope of duties of workers,
    2) Request explanations in case of doubts regarding the confirmation of the fulfillment of the aforementioned requirements,
    3) Conduct inspections at the place of contract performance.
4. In case of failure by the Contractor or subcontractor to meet the requirements concerning employment based on an employment contract for persons performing the activities specified in paragraph 1 above, the Ordering Party provides for a sanction in the form of an obligation for the Contractor to pay a contractual penalty of ... PLN for each case. The failure by the Contractor or subcontractor to submit the documents requested by the Ordering Party within the time specified by the Ordering Party, as referred to in paragraph 3 point 1 above, to confirm the fulfillment of the requirements concerning employment based on an employment contract, will be treated as a failure by the Contractor or subcontractor to meet these requirements.
5. The Contractor declares and guarantees that the subcontractor will comply with the above obligations, and the contract concluded between the Contractor and the subcontractor will contain provisions analogous to those described in this paragraph.

§ 20

Final provisions

1. All changes or amendments to this Agreement shall require the form of a written document under pain of nullity.

2. Matters not regulated in this Agreement shall be governed by the provisions of Polish law, including the Civil Code, with the reservation of the provisions of Articles 431-465 of the Public Procurement Law.

3. In the event of a conflict between the provisions of this Agreement and the attached documents, the provisions of this Agreement shall take precedence to the extent that the Agreement is able to specify.

4. Disputes arising from the implementation of this Agreement shall be resolved amicably within 60 days, based on the provisions of Polish law, and in the event of failure to reach an agreement, the dispute shall be referred for resolution through judicial proceedings before the competent common court for the domicile of the Ordering Party.

5. This Agreement has been drawn up in four identical copies, three for the Ordering Party and one for the Contractor.

6. The following Appendices constitute an integral part of the Agreement:

Attachment No. 1 - Contractor's Offer dated .....;
Attachment No. 2 - Detailed Cost Estimate with Schedule;
Attachment No. 3 - Description of the Subject of the Order;
Attachment No. 4 - List of Persons Responsible for the Execution of the Order on the Contractor's Side;
Attachment No. 5 - List of Persons Responsible for the Execution of the Order on the Ordering Party's Side;
Attachment No. 6 - Model of Partial Acceptance Protocol;

_____	_____
Contractor	Ordering party

Annex No. 6 to the Agreement

Partial Acceptance Protocol

Symbol and name of the destination unit:

.....

.....

Phone no. .....

Lp.	Subject of acceptance (tasks/activities)	Category of task/activity according tobAnnex 5 (A, B, C, D or E)	Item number In Annex No. 5
1.			
2.			
....			

I*) Accepted on .....with comments .....

Deadline for corrections: .....

The seal of the Ordering Party	The seal of the Contractor
Signature and stamp of the authorized person on the part of the Ordering Party	Signature and stamp of a person authorized by the Contractor

II *) Accepted without comments on the day:..... .....

The seal of the Ordering Party	The seal of the Contractor
Signature and stamp of the authorized person on the part of the Ordering Party	Signature and stamp of a person authorized by the Contractor

NOTE: The above protocol signed 'without reservations' is the basis for issuing the VAT invoice

Annex No. 7 to the Agreement

Final Acceptance Protocol

Symbol and name of the destination unit:

……

……

Phone no. ……

Lp.	Subject of acceptance (tasks/activities)	Category of task/activity according tobAnnex 5 (A, B, C, D or E)	Item number In Annex No. 5
1.			
2.			
….			

I*) Accepted on ……with comments ……

Deadline for corrections: ……

The seal of the Ordering Party	The seal of the Contractor
Signature and stamp of the authorized person on the part of the Ordering Party	Signature and stamp of a person authorized by the Contractor

II *) Accepted without comments on the day:…… ……

The seal of the Ordering Party	The seal of the Contractor
Signature and stamp of the authorized person on the part of the Ordering Party	Signature and stamp of a person authorized by the Contractor

NOTE: The above protocol signed 'without reservations' is the basis for issuing the VAT invoice