**Contract No.**[[1]](#footnote-1)

Concluded [ ]  in writing on 1            / [ ]  in electronic form [[2]](#footnote-2)

between:

**POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A. (POLISH CENTRE FOR TESTING AND CERTIFICATION),** 469 Puławska Street, Warszawa, 02-844, the company registered in the National Judicial Register under KRS No. 0000144813 in XIII Economic Division of Capital City of Warsaw Local Court; initial capital 16,000,000 PLN entirely paid; NIP (tax identification number) 951-20-63-356; hereinafter referred to as „**PCBC”**, represented under a power of attorney granted by the Management Board of the PCBC, by 1

**and**

**,**       Street, city      , zip code:      , registered in       ; NIP (tax identification number)      ; referred to as „**Organization”,** represented by:

-

or

**-**       **conducting business activity under the name:**      ,       Street, city      , zip code:      , under registration in      , NIP (tax identification number:      , referred to as „**Organization”**, operating under this Contract personally/represented on the basis of       by:

 **1. Subject of the Contract**

1. The subject of this Contract shall be to define the principles of cooperation, rights and obligations and mutual obligations of Parties related to certification process of management system of the Organization in accordance with the standard(s) serving as certification criterion (hereinafter referred to as “System”) and to define rules of System surveillance.

2. Standards and a type of audits being the subject of this Contract, in the certification cycle, shall be defined in the approved Cost estimate constituting Appendix 1 to this Contract.

3. The Organization branches/locations covered by the process in accordance with the “Application for certification by the PCBC” submitted by the Organization shall be specified in the Cost estimate.

 **2. General provisions**

1. The process shall commence upon signing this Contract by the Parties, after prior acceptance by the Organization of the Cost estimate referred to in § 1 (2) of this Contract.
2. The System Certificate shall be granted to the Organization after positive decision of the PCBC on management system certification. The System Certificate (hereinafter referred to as “Certificate”) shall mean: a document issued in accordance with the principles of the certification process proving the conformity of management system with reference documents (standards constituting the basis for certification). The Certificate shall bear a qualified electronic signature.
3. The Certificate granted after initial certification audit shall be valid for three years from the date of the PCBC decision on the System certification. The Certificate granted after re-certification audit shall be valid for three years in accordance with the certification cycle. In case of audit of the transition to the new edition of the standard/requirements during the surveillance audit or transfer of an accredited certification, the Certificate shall be granted in accordance with the Organization’s current certification cycle. In case of a positive decision of the PCBC to grant the Certificate, the Organization shall be informed about it to the e-mail address of the Organization's coordinator provided in § 9. In case of refusal to grant the Certificate, the decision of the PCBC on the System certification shall be sent to the Organization to the e-mail address of the Organization's coordinator provided in § 9. The prerequisite to maintain the validity of the Certificate during its validity shall be the positive results of annual surveillance audits carried out in accordance with § 5 of this Contract.
4. The validity of the Certificate may be renewed for a period of next three years, on the basis of this Contract or a separate one, after System re-assessment and prior acceptance by the Organization of the PCBC offer in this scope.
5. All audits shall be carried out by Auditors authorized by the PCBC.
6. The transfer of certification shall be carried out in accordance with the requirements of IAF MD 2. In this case, the Organization shall submit to the PCBC the completed FBC 46 form “Declaration on the transfer” with required attachments together with the signed Contract (*applicable to: the process of transferring accredited certification*).
7. The Certificate shall be the property of the PCBC and this right shall not be assigned (waived/transferred) to third parties. The withdrawal of the Certificate shall cause its validity to become invalid. The Organization (certified entity) as the holder of the Certificate shall be entitled to use it in the scope specified in § 4 below. The PCBC shall remain the owner of the data provided in the Certificate.
8. Each audit report shall be the property of the PCBC. Dissemination of the report as an integral whole by the audited Organization shall not be not restricted. The Organization shall not be entitled to violate the integrity of the report and to split it including combine the report or its parts with other works as well as to use parts of the report in trading.
9. The scope of certification shall be defined in the “Application for estimate of the certification by the PCBC”. The certified scope shall be verified during the application review and during the audit. The detailed verified scope of certification shall be accepted by the Organization in the part of the report concerning the content of the Certificate.
10. All audits in the certification cycle shall be conducted and documented in English. The System documentation shall be available in English.
11. It shall be allowed to change the date of the audit in case of changes in the Organization regarding in particular: employment status, scope of certification, number of locations, with the proviso that:

a) if the change is significant in the opinion of the PCBC, it shall require a change of the data by the Organization in the “Application for estimate of the certification by the PCBC” as well as a change in the amount of remuneration for the PCBC relevant to the scope and subject of changes in the Organization;

b) each such change shall require this Contract to be annexed each time and the dates of surveillance audits set by the change shall not be later than the dates provided in this Contract.

12. Regardless of the content of § 2 (11), before each subsequent audit in the certification cycle the PCBC shall request the Organization to determine whether there have been significant changes to the Organization. The changes referred to in particular (but not exclusively) concern: changes in the number of persons covered by the system; extension of the scope of the granted certification with new system(s)/new location(s)/new process(es); limitation of the scope of the certification granted by one (several) system(s)/one (several) location(s)/one (several) process(es).

13. In addition, the PCBC shall reserve the right to request changes to the amounts due or costs specified in the cost estimate in case of:

a) non-compliance of the facts with the data provided by the Organization in the “Application for estimate of the certification by the PCBC”;

b) when the Organization using suppliers of processes or parts that are critical for the functionality of the medical device and/or the safety of the user of finished products, including products under own brand, cannot provide sufficient evidence of conformity with the audit criteria. In such situation the PCBC shall be entitled to extend the audit time (to add additional audit time including audit at suppliers) as well as to request the Organization to bear additional costs - dues for additional audit time including dues related to the audit at suppliers (*applicable to: ISO 13485*).

14. The Organization shall have the right to apply for a change in the scope of certification also beyond the dates of audits in the cycle.

15. In cases resulting from the content of § 2 (12, 13 or 14) the PCBC shall assess whether the changes (defined by the Organization as a result of the request of the PCBC or requested by the Organization) require the Organization to change the data in the “Application for estimate of the certification by the PCBC” as well as whether they cause changes in the amount of remuneration for the PCBC relevant to the scope and subject of the changes and shall inform the Organization about it. In case that changes require the Organization to change the data in the “Application for estimate of the certification by the PCBC” or cause changes in the remuneration of the PCBC relevant to the scope and subject of the changes, further implementation of this Contract by the PCBC shall take place only after:

a) conclusion relevant Annex to this Contract by the Parties (including also the deadline for the performance of actions by the PCBC) or

b) the Parties sign a new Cost estimate that shall replace the valid Cost estimate without the need this Contract to be annexed when the changes affect only the remuneration due to the PCBC.

In each of the above cases the liability of the PCBC for non-performance or improper performance of this Contract, including on the originally specified dates, or due to the expiry of the Certificate validity, shall be excluded.

 **3. Obligations and rights of the PCBC**

1**.** The PCBC shall be obliged:

1) to protect and keep confidential, in accordance with § 10 and with the proviso of § 3 (2) (8 and 9): data entrusted for the purposes of the subject of this Contract, collected, processed, stored, maintained, shared and updated in accordance with Art. 28 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) and in accordance with Act of 10 May 2018 on the protection of personal data (Dz.U. 2019 item 1781) and any other data constituting a trade secret of the Organization obtained during the performance of this Contract, as well as to maintain confidentiality of information about the Organization originating from sources other than the Organization (e.g. from the complainant, public office, etc.), in accordance with the policy of the PCBC;

2) to agree reference documents or other regulations being a basis for the assessment of the System and implementation of process according to binding procedures;

3) to award a Certificate to the Organization proving conformity of the System with reference documents being a basis for assessment provided that conditions specified in § 2 (2) are met;

4) to perform surveillance audits in the Organization in accordance with § 5 hereof;

5) to evaluate sufficiently objective evidence that is the basis for certification decision;

6) to provide the Organization with a written decision together with reasons in case of negative results of audit;

7) to send audit reports within 30 working days from the date of completion of the audit. Each audit report shall be send to the e-mail address of the Organization's coordinator provided in § 9;

8) to provide the Certificate to the e-mail address of the Organization’s coordinator provided in § 9 − together with the marks of certified System − within two weeks of the date of settlement by the Organization of all financial commitments related to completed audit, specified in accepted Cost estimate constituting Appendix 1 hereto. In each case the Certificate shall be provided after all fees due to the PCBC, related to the certification process in accordance with the provisions hereof and the stage of the certification process being implemented, are paid;

9) to provide the IQNET certificate together with relevant mark (*applicable to: ISO 9001, ISO 13485*)to the e-mail address of the Organization’s coordinator provided in § 9; within terms provided above in 8);

10) to notify the Organization on changes concerning certification requirements to the e-mail address of the Organization’s coordinator provided in § 9.

2. The PCBC shall have the right:

1. to require from the Organization to analyse causes and describe measures taken or planned, relevant corrections and corrective actions to eliminate nonconformities detected;
2. to review the evidence proving performance of corrections and corrective actions submitted by the Organization to determine if they are acceptable;
3. to restrain issue of the Certificate until the Organization meets commitments arising from this Contract, in particular as regards failure to perform actions related to corrections and/or corrective actions and to pay required fees;
4. to perform full or limited additional audit, in particular cases, before awarding the Certificate and also during the Certificate validity period. Such cases shall refer to necessary verification of the effectiveness of the corrections and corrective actions taken as a result of detected nonconformities;
5. to appoint and change audit team in the process defined in § 1 with taking rights of the Organization specified in § 4 (1) (1) into account;
6. to carry out review of application and define all audit actions necessary to make decision in the process defined in § 1 responding to “Application for estimate of the certification by the PCBC” submitted by the Organization;
7. to perform special audits so-called audits with short term of notification (minimum 14 days before the audit), or without notification:
	1. to investigate complaints,
	2. responding to changes,
	3. within further proceeding with suspended certifications,
	4. when devices covered by the scope of certification indicate a possible significant deficiency in the quality management system (*applicable to: ISO 13485*),
	5. when significant safety and performance related information becoming known to the PCBC (*applicable to: ISO 13485*),
	6. when required by legal regulations (requirements) under public law or by the relevant Regulatory Authority (*applicable to: ISO 13485*);
8. to share the Organization's data including information contained in audit reports with members of the Committee for Impartiality Assurance who have signed an appropriate commitment to maintain the confidentiality of information, as well as with the Polish Centre for Accreditation (PCA) as the PCBC supervisory authority and having the right to access documentation from the certification process under the provisions of the Act on Conformity Assessment and Market Surveillance Systems;
9. to share the Organization's data including information contained in audit reports to the competent authorities, within the meaning of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC or Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU *(applicable to: ISO 13485);*

3. In case of incorrectness defined respectively in § 3 (2), the PCBC shall have the right to suspend, withdraw or limit the scope of the Certificate according to provisions of paragraphs 4 - 6 below. The PCBC shall notify the Organization in writing of the actions undertaken.

4. The suspension of the Certificate shall take place in the following cases:

1. the certified management system of the Organization constantly or to a large degree does not meet certification requirements including requirements on management system’s effectiveness;
2. the Organization refuses consent to surveillance audits or re-certification audits to be performed with required frequency specified in the § 5 hereof;
3. at the request of the Organization;
4. revealed breach by the Organization of rights and duties specified herein;
5. failure to observe rules provided in the § 7 hereof;
6. failure to settle financial commitments to the PCBC in fixed term;
7. failure to fulfil by the Organization the obligations determined by this Contract, including the ones provided in § 4 (2);
8. medical incident in the meaning of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC or Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU occurred in the Organization (*applicable to: ISO 13485*).

The suspension period of the Certificate shall not exceed six months. During suspension period the certification shall be temporarily invalid. In case of suspension the Organization shall restrain from further promoting of its certification.

The PCBC shall resume suspended certification if issues resulted in suspension have been resolved by the Organization.

5. The certificate shall be withdrawn in the following cases:

1. issues resulting in the suspension of the Certificate have not been solved in term fixed by the PCBC;
2. lasting discontinuation of: conducting business, rendering services or operating processes covered by scope of the Certificate has been stated;
3. termination of this Contract.

Upon withdrawal of the Certificate, the Organization shall be obliged to stop referring to the status of Certified Organization and using certificates in all activities and commercial, promotional and advertising documents.

6. The scope provided in the Certificate shall be limited in the following cases:

1. issues resulting in limitation of the scope of the Certificate have not been solved in term fixed by the PCBC;
2. with the purpose to exclude these parts which do not meet requirements when the Organization permanently or to a large degree does not meet certification requirements for these parts of the certification scope;
3. at the request of the Organization.

Any limitation shall meet requirements of the standard applied for certification.

 **4. Rights and obligations of the Organization**

1. The Organization shall have the right:

1. to request for change of particular members of audit team in situation of conflict of interests, especially when a member of audit team is a former employee of audited Organization or has rendered consulting services for the Organization and also in case of earlier non-ethical behaviour. A request to change shall be submitted within five days of receipt of information from the PCBC on composition of audit team. In justified cases the PCBC shall change members of proposed composition of audit team;
2. to make reference to the Certificate and certified management System:

a)in advertising and promotional activities,

b) during negotiations, concluding agreements and contracts concerning field of activity covered by the scope of the Certificate and certified management System indicating that the Certificate shall relate to the System specified herein;

1. to use marks of certified System according to § 7 hereof;
2. to request the PCBC to keep confidential any information being business secret obtained from the Organization (especially during audits) with the exception of cases provided by law and regulated herein;
3. to lodge claims and appeals related to the process, according to § 6 hereof;
4. to request for change of the scope provided in the Certificate already awarded by the PCBC. In such case a way and scope of assessment and related costs shall be defined in accordance with duly applied provisions of § 2 (13) and (15);
5. to request for discontinuation of certification process regarding conditions referred to in § 8 (6) hereof.

2**.** The Organization shall be obliged:

1. to ensure availability of resources and facilities necessary for work of audit team and access to all processes, areas including the creation of conditions for auditing temporary locations, records and personnel for purposes of certification, surveillance, re-certification, transfer of certification and handling of complaints;
2. to settle on time all financial commitments to the PCBC, in accordance with terms established herein, related to the process defined in § 1;
3. to remove detected nonconformities with requirements of standard(s) applied to the process defined in § 1 and to submit evidence of their correction;
4. to maintain its System conforming with requirements of reference document(s) as referred to in the Certificate;
5. to keep records on claims lodged by customers of the Organization and make them available to the PCBC and its auditors and to take regular corrections and corrective actions related to the System;
6. to notify the PCBC immediately of organizational and legal changes, changes in activity and management, especially referring to legal status, data of the Organization, organizational and management structure, scope of activity covered by certified management System and main changes in System and processes;
7. to notify the PCBC immediately of occurring medical incidents in the meaning of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC or Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (*applicable to: ISO 13485*);
8. to follow decisions of the PCBC concerning changes of requirements in the process defined in § 1;
9. to make reference to Certificate held and certified management System only in relation to organizational structure (head office, branch, unit, division, etc.) covered by certification;
10. not to extend the scope of the Certificate to the organizational structures not covered by certified System;
11. to discontinue making reference to Certificate from the date of expiration of its validity or date of receipt of the PCBC’s decision on suspension or withdrawal of the Certificate, especially to discontinue using information about Certificate held in promotional materials;
12. to return any certification documentation after withdrawal of the Certificate if it was issued in paper version;
13. to enable participation, as observers, in management system audits (participation in observation) to:
14. auditors of the PCA accreditation body (Polish Centre for Accreditation),
15. auditors of the PCBC conducting periodic evaluation of auditors,

c) candidates for auditors of the PCBC.

Refusal by the Organization of participation of persons specified in § 4 (2) (13) (a) and (c) in the observation must be justified and submitted to PCBC in writing. In case of participation in the observation conducted by the auditors of the PCA accreditation body, the refusal by the Organization of their participation in the observation and its justification must be submitted to PCBC in writing or via e-mail and additionally be approved by both the PCBC and the PCA. The consequence of failure to provide the PCBC the Organization's position on the refusal of participation in the observation or justification, as well as no acceptance by the PCBC or the PCA of the aforementioned position of the Organization on refusal to participate in the observation may be the withdrawal of the Certificate.

The participation of observers shall not burden the Organization financially and the costs related to participation of observers in the audit shall be covered by the PCBC.

 **5. Surveillance, re-certification**

1. The Organization shall demonstrate that it permanently meets requirements of the standard concerning certified System.
2. The certified Organization shall be responsible for continuous achieving the intended results of the implementation of the System standard(s) and for conformity with certification requirements.
3. Surveillance audits shall be conducted minimum once a calendar year with the exception of years in which re-certification is to be conducted.

Date of the first surveillance audit after initial certification shall not be later than 12 months from the date of decision on certification of the System. The second surveillance audit shall be conducted before 24 months from the date of decision of the PCBC on certification of the System.

1. The re-certification audit shall be conducted not later than 3 months before expiration date of the Certificate considering that the PCBC must plan the re-certification audit in such a way as to give the Organization appropriate time for elimination of possible nonconformities before expiration date of the Certificate. Failure to remove nonconformities before expiration date shall result in loss of its validity (expiration) on the date of validity expiration of the Certificate. If the PCBC cannot verify implementation of corrections and corrective actions regarding nonconformities before expiration date of the valid Certificate, the re-certification shall not be recommended and the validity of the Certificate shall not be extended.
2. After expiration of the Certificate validity (expiration of certification) in accordance with § 5 (4) the PCBC may conduct re-certification process provided that all not executed activities, including making decision on re-certification, are completed within six months after the expiration of the Certificate validity. Possible applying by the Organization for certification after six months from the expiration of the Certificate validity shall imply a need to conduct initial certification, including submission of the “Application for certification by the PCBC” by the Organization which results in a need to conduct two-stage certification audit.
3. Audit activities related to re-certification may require to conduct the first stage of audit in cases of significant changes in the System of the Organization or in the context in which the management System operates (e.g. legislative changes).
4. In each case, the condition for conducting surveillance audits or a re-certification audit shall be the payment by the Organization of all amounts due to the PCBC related to the certification process in accordance with the provisions hereof and the stage of the certification process being implemented. In case of the Organization failure to make payment, the PCBC may refuse to carry out surveillance audits, which shall result in the suspension of the Certificate.

 **6. Claims and appeals**

* 1. The Organization shall have the right to lodge a complaint on proceeding of the process defined in § 1 including the right to lodge a complaint regarding work of auditors. Complaints shall be lodged according to the procedure provided on the website www.pcbc.gov.pl.
	2. The Organization shall have the right to submit an appeal against a decision of the PCBC. Appeals shall be lodged according to the procedure provided on the website www.pcbc.gov.pl.
	3. The principle of impartiality and confidentiality shall be observed at all stages of proceeding in processing complaints/appeals.

 7. Rules of use of certified System marks

1. The certified Organization shall refer to the PCBC’s certification through wording reference and/or use of certification marks on terms specified in updated document DBC 13 “Rules for Use of Certified System Marks”.

The aforementioned document shall be publicly available on the website www.pcbc.gov.pl.

2. Certification shall not be a full and continuous guarantee of legal compliance however it shall be a proven and effective tool to achieve and maintain legal compliance and shall provide top management with relevant and up-to-date information regarding the Organization's compliance status.

3. In case of loss of validity (expiration), withdrawal or limitation of the scope of the Certificate or termination of this Contract, the Organization shall be obliged to cease using the Certificate awarded under the agreement and immediately return all originals of the Certificate (if issued in paper form) to the PCBC, and to immediately stop using the marks referred to in § 7 (1).

 **8. Payment for services**

1. The Organization whose business activity is registered in Poland shall declare that it is an active VAT payer. For the organization whose business activity is registered in the European Union (outside Poland) it shall be required to provide the EU VAT contract in the comparison. For the Organization whose business activity is registered outside the European Union it shall not be required to provide EU VAT.
2. Singing this Contract the Organization shall be obliged to bear charges and costs related to certification in currency specified in Cost estimate. Payment shall me made to the PCBC bank account provided in the invoice issued by the PCBC in currency complying the currency specified in Cost estimate and in the invoice. Numbers of the PCBC bank accounts for relevant currencies:
	1. PLN: 90 1240 6003 1111 0000 4946 7594,
	2. EUR : 52 1240 1040 1978 0010 6585 1963,
	3. USD: 24 1240 1040 1787 0010 9968 2328.

All bank transfer fees including transfer related to payment in currency other than PLN shall be borne by the Organization. Upon making payment the Organization shall be obliged to pay bank transfer costs in accordance with fees charged by banks.

1. A Cost estimate shall be an integral part of this Contract in accordance with provisions of § 1. A Cost estimate shall include an information accepted by the Organization about planned dues for particular stages of the certification process and costs related to certification process. Dues shall be provide in net amount (i.e. without value added tax or other taxes resulted from the Organization seat) in a currency resulting from Cost estimate. If applicable, dues or costs shall be increased by value added tax in accordance with applicable law.
2. The Organization shall make payment for the stages of the certification process specified in the Cost estimate and shall be also obliged to cover - in accordance with this Contract - the costs of which the maximum amount is specified in the Cost estimate.
3. Payment of dues referred to in § 8 (4) shall be made by the Organization on the basis of an invoice sent by the PCBC, within the payment period specified on the invoice – not shorter than 14 days, as follows:
4. 70% of the total amount estimated by the PCBC in Cost estimate due to the PCBC for the stage of the certification process – after the audit conducted by the PCBC;
5. 30% of the total amount estimated by the PCBC in Cost estimate due to the PCBC for the stage of the certification process - after completion of the stage of the certification process considered as taking decision in the certification process by the PCBC. In each case the Organization shall be informed about the decision made in the certification process for e-mail address of the Organization’s coordinator provided in w § 9.

Depending on the stage of the certification process, the decision referred to in above shall concern:

1. in case of initial or re-certification audit – awarding or refusal to award the Certificate;
2. in case of each surveillance audit conducted in accordance with 5 hereof – maintaining or suspension or withdrawal of the Certificate.

The Organization shall agree to receive invoices by electronic means sent to the Organization by the PCBC from the e-mail address: faktury@pcbc.gov.pl to the e-mail address of the Organization:      .

6. Termination of this Contract or discontinuation of the certification process, regardless of the basis or reason, shall not constitute grounds for the Organization's refusal to pay to the PCBC charges for the performance of particular actions as part of the certification process - with the proviso that in such case the PCBC dues shall be determined as a percentage in accordance with the state of advancement of actions conducted by the PCBC in the aforementioned process. In addition, in case referred to in the first sentence of this provision, the Organization shall obliged to bear additional costs referred to in § 8 (7-8) if they are justified.

7. Notwithstanding the above dues to the PCBC for performing actions in the certification process, the payment referred to in § 8 (5) (b) for the stage of the certification process shall be increased by accompanying costs, i.e. travel and accommodation costs of the auditor(s) and expert(s) - up to the amount resulting from the Cost estimate. If the Organization provide appropriate means of transport and accommodation for the auditor(s) and expert(s), travel time and accommodation must be arranged in such a way that they do not affect the audit plan and activities undertaken by the PCBC. If it is necessary to use the services of an interpreter in the certification process - in particular with regard to the System documentation prepared in a language other than English – the Organization shall be obliged to ensure the participation of an interpreter in the certification process and cover the costs of the services provided by him.

8. The costs of special and additional audits carried out in accordance with § 3 shall not be included in the Cost estimate and in case such costs occur they shall be borne by the Organization.

9. The PCBC shall declare that the bank account provided by the PCBC in this Contract or on the invoice, as the relevant one to perform settlements under this Contract, shall be in each case an account reported to the tax authorities and listed in the register of VAT taxpayers. If it is identified before making the payment that the bank account provided by the PCBC is not reported to the tax office, i.e. it does not appear on the so-called "white list of VAT taxpayers", the Organization shall inform the PCBC about this fact to submit an explanation within no more than 7 working days. In this case, the Organization shall be entitled to withhold payment without exposing itself to any obligation to pay interest, damages or any other additional costs. A change or providing of an additional bank account shall not require this Contract to be annexed but it shall be necessary to report such a change together with a statement that the account is reported to the tax authority.

10. Regardless of the content of § 8 (5) if the Organization is in delay with the payment of any of the dues covered by the invoice issued by the PCBC in accordance with § 8 (5) by a period exceeding 30 days, the PCBC shall be entitled, before commencement of the next stage of the certification process in accordance with this Contract, to issue - before the next stage - a proforma invoice in the amount corresponding to 100 % of the total amount estimated by the PCBC S.A. in the Cost estimate due to the PCBC for conduction the particular stage of the certification process. In this case:

a) the PCBC shall commence the stage of the certification process only when the Organization pays the overdue amount and the amount covered by the proforma invoice - deadlines for implementation by the PCBC of activities resulting from this Contract shall be postponed without the need this Contract be amended by an annex, and

b) responsibility of the PCBC for non-performance or improper performance of this Contract, including on the originally specified dates or due to the expiry of the Certificate validity shall be excluded.

**§ 9. Notifications**

1. For the purpose of the ongoing performance and implementation of this Contract and for contacts between the Parties, as well as for performing other actions identified in this Contract, the Parties shall appoint and authorize their Coordinators:
2. Coordinator from the PCBC:

      e-mail:       telephone number: +

1. Coordinator from the Organization:

      e-mail:       telephone number: +

1. Each Party shall have the right change the own Coordinator or the details of the own Coordinator by notifying the other Party in writing. Such change shall not constitute a change to this Contract. The change of the Coordinator shall take effect upon delivery of information about the change of the Coordinator or change of data concerning the Coordinator to the other Party.
2. With the exception of those actions for which this Contract clearly indicates that they are to be made in writing (in writing, in written form or require to be signed by the Parties) or for which a written form is required by law, all correspondence of the Parties shall be made via e-mail addressed to the addresses and numbers of persons indicated in § 9 (1) (subject to the content of § 9 (2)) unless this Contract clearly indicates that the e-mail correspondence shall be an acceptable form of delivery for and action made in writing.
3. Subject to the content of § 9 (3) the Parties shall agree that the basic means used for ongoing communication between the Parties shall be e-mail. In case of deliveries made via e-mail, a document shall be deemed to have been delivered upon it is uploaded to the network in such a way that the other Party could read its content.
4. Notifications made in writing shall be delivered by registered mail or courier services with acknowledgment of receipt. A notification made in writing shall be deemed delivered:
5. n case of a registered letter, upon receipt of a registered letter or the expiry of the deadline for receipt of this letter, and
6. in case of delivery via courier services: upon delivery to the notifying Party of confirmation of receipt or confirmation of refusal of receipt (regardless of the reason).

If it is necessary to perform actions in writing, and also to deliver an invoice, a correspondence shall be sent to the addresses of the Parties identified in the comparison of this Contract.

**§ 10. Personal data, confidentiality**

* + - 1. The Parties shall be obliged to process personal data in accordance with applicable law, including GDPR (including: personal data provided by the other Party for the purpose of and as a result of conclusion and performance of this Contract, including individuals representing or being a Party to this Contract, associates, employees, subcontractors, employees and associates of subcontractors, as well as other individuals whom the Party to this Contract uses to perform this Contract, statutory representatives, representatives and attorneys of the other Party to this Contract).
			2. The Organization shall provide the PCBC with an information clause for contractors, the content of which shall contain the information required under Art. 13 and 14 of GDPR. The indicated clause shall constitute an Appendix to this Contract. The PCBC shall declare that the above-mentioned clause is read and its content accepted by the PCBC.
			3. The PCBC shall be obliged to fulfil the information obligation within the time limits provided in GDPR towards all individuals referred to in § 10 (1) on behalf of the Organization acting as the administrator of personal data.

If during the performance of this Contract the PCBC performs, on behalf of the Organization, activities related to processing of personal data of individuals other than those listed in § 10 (1), whose administrator of personal data is the Organization, the PCBC shall be obliged to fulfil an information obligation on behalf of the Organization also towards these individuals.

* + - 1. The PCBC shall provide the an information clause for contractors, the content of which shall contain an information required under Article 13 and 14 of the GDPR. The indicated clause shall constitute an Appendix to this Contract. The Organization shall declare that the above-mentioned clause is read and its content accepted by the Organization.
			2. The Organization shall be obliged to fulfil the information obligation within the time limits provided in GDPR towards all individuals referred to § 10 (1) on behalf of the PCBC acting as the administrator of personal data. If during the performance of this Contract the Organization performs, on behalf of the PCBC, activities related to processing of personal data of individuals other than those listed in § 10 (1), whose administrator of personal data is the PCBC, the Organization shall be obliged to fulfil an information obligation on behalf of the PCBC also towards these individuals.
			3. If the processing of personal data is entrusted during the implementation of this Contract, the Organization shall sign an agreement with the PCBC, requested by law, on mutual transfer of data.
			4. With the proviso to other provisions of this Contract regarding the right or obligation of the PCBC to disclosure an information, including Confidential Information (as defined below), each Party shall undertake to keep secret and not to use any information and data disclosed to it in a manner other than in accordance with this Contract. Each Party shall acknowledge that any information and data provided by the other Party during performance of this Contract (including in particular technical, technological, organizational, economic, commercial and legal data) as well as all information and materials created during performance hereof (written, graphic, saved in electronic form or otherwise) shall be confidential and shall not be made available or disclosed to any third party without the prior written consent of the other Party - they constitute confidential information and business secret of the disclosing Party and shall be protected by this title (Confidential Information).
			5. The obligation to maintain confidentiality and the obligation to protect Confidential Information shall expire after 10 years from the disclosure of Confidential Information.
			6. Provisions of § 10 shall not apply in the following cases:
1. Confidential Information was publicly available on the date of providing it by the disclosing Party;
2. when Confidential Information must be disclosed in accordance with the law or court decisions or at the request of authorized state authorities, EU administration authorities, supervisory authorities (PCA);
3. when Confidential Information must be disclosed to perform this Contract, with the proviso to § 10 (10).
	* + 1. The Parties shall use obtained Confidential Information only to perform this Contract and shall not use it for any other purpose.
			2. The PCBC shall disclose Confidential Information only to its (respectively) employees/auditors/ experts/ subcontractors who are directly involved in the performance hereof and only to the extent necessary for its performance, and provided that these persons undertake to maintain confidentiality in accordance with the provisions of this paragraph. Notwithstanding the above, the PCBC shall disclose Confidential Information to state authorities, EU administration authorities or supervisory authorities.
			3. Each Party shall undertake to destroy (respectively remove) or return (at the Party's decision) all materials (respectively files containing Confidential Information held by the Party) immediately, and in any case within 7 days from the date of receipt of the other Party's request at the latest.
			The aforementioned obligation shall not apply to Confidential Information that the Party shall be obliged to store or disclose in accordance with the obligation resulting from generally applicable laws, court decision or disclose at the request of an authorized state administration authorities, EU administration authorities, supervision authorities (including PCA), including where they have been recorded in electronic form.
			4. Each Party shall undertake to ensure appropriate storage conditions for any Confidential Information, regardless of whether the Confidential Information is expressed in intangible or tangible form, in a manner that prevents unauthorized access to it.

In particular, the Parties shall be obliged to make every effort to ensure that the means of communication used by them to receive and transmit Confidential Information guarantee the protection of this information against access by unauthorized persons.

#  11. Final provisions

1. This Contract shall be valid from the date of its conclusion till the date of the Certificate expiry.
2. In case of the Certificate validity expiration or withdrawal of the Certificate this Contract shall be terminated accordingly:
3. on the date of the Certificate validity expiration or
4. on the date of delivery of the PCBC’s decision on withdrawal of the Certificate to the Organization in accordance with the provisions hereof.
5. This Contract can be terminated regardless of the reason by either Party with one month written notice starting from the first day of the month following the month in which termination was made. This Contract can be terminated at any time by agreement of the Parties.
6. The PCBC shall have the right to terminate this Contract immediately, i.e. without notice period defined in § 11 (3) in case of:
7. failure by the Organization to pay charges specified in § 8 within the time limit determined in this Contract as well as in case of failure by the Organization to fulfil the obligations set out in § 4,
8. in case of a gross violation by the Organization of other provisions of this Contract or legal provisions relevant to the subject hereof.
9. Termination of this Contract (including as a result of its termination or termination by agreement of the Parties) shall result in the loss of validity (expiry) of the Certificate on the date of termination hereof which shall be tantamount to withdrawal of the Certificate granted by the PCBC on the date of termination of this Contract.
10. Without prejudice to the provisions of § 11 (5), during the validity period of the Certificate referred to in § 11 (5), all obligations arising from this Contract shall apply to the Organization.

7. Responsibility of the PCBC for damages resulting from non-performance or improper performance of the provisions of this Contract, as well as for termination of this Contract before its expiry for reasons attributable to the PCBC, and also liability for damages resulting from other reasons (e.g. tort) and damages caused by subcontractors of the certification body (including experts and auditors) shall be limited to the dues paid to the PCBC under this Contract. Responsibility of the PCBC shall not include lost profits within the meaning of Art. 361 of the Civil Code.

8. Liability of the Parties for non-performance or improper performance of the obligations defined in this Contract shall be excluded if the non-performance or improper performance is directly caused by Force Majeure. By Force Majeure, the Parties shall understand any event beyond the control of the Parties.

9. The following events shall be considered Force Majeure:

1. elements of nature, flood, accident, fire, explosion, epidemic,
2. acts of war, threat of war, terrorism, mobilization, riot, rebellion, sabotage, insurrection, civil disorder or requisition,
3. strikes, lockouts or other commercial or industrial disputes involving employees of the Organization or the PCBC,
4. technical failures in the area where the PCBC actions are performed under this Contract, including on the premises of the Organization's site, which may result in death or serious damage to health of persons implementing the subject of this Contract.

The following events shall not be considered Force Majeure:

* 1. events caused by negligence or intentional omissions/activities of the Party or Parties, their suppliers/service providers, agents, co-operators or employees, auditors/experts,
	2. weather conditions that could have been foreseen by the Party or suppliers/service providers/auditors/subcontractors,
	3. no sufficient financial or technical resources for the implementation of the subject of this Contract.

10. The Party referring to Force Majeure shall obliged to immediately notify the other Party, no later than five days from its occurrence. The cessation of Force Majeure shall be notified to the other Party immediately.

11. If Force Majeure lasts more than four weeks, the Parties shall start talks to determine new terms of this Contract or terminate it.

12. Termination of or changes to this Contract shall be made in written form in order to be valid.

13. This Contract shall be governed by the laws of Poland. Fulfilment by any of the Parties of the obligations imposed by the tax law of the country competent for the Party’s tax jurisdiction in reference to services provided by the PCBC under this Contract, each time shall take place with regard to the provisions of the relevant agreement on the avoidance of double taxation (determined with regard to the countries of residence of the Parties to this Contract).

14. Regarding issues not covered by this Contract the relevant provisions of the Civil Code and the GDPR shall apply.

15. Any disputes that may arise during the implementation of this Contract shall be resolved through negotiations. In case of inability to resolve disputes including, among others, interpretation or performance of this Contract through negotiations, disputes shall be settled by the court competent for the seat of the PCBC according to Polish law.

16. This Contract is made out in two counterpart originals, one original for each Party. The date of conclusion of this Contract shall be considered the date of its signing by the PCBC *(applicable to: contract concluded in writing*).

17. This Contract was concluded in electronic form with qualified electronic signatures by persons representing each of the Parties. The date of conclusion of this Contract shall be considered the date of placing the last qualified electronic signature by the person representing the Party who signed as the last one *(applicable to: contract concluded in electronic form)*.

This Contract is signed by:

###  For the PCBC For the Organization

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Appendices:

1. Cost estimate
2. Information obligation implemented by the Parties.

# Appendix 2 to Contract no                                     of

(Contract for management system certification)

**Information obligation implemented on behalf of the PCBC**

Fulfilling the obligation arising from the 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) hereinafter referred to as GDPR - please be informed that:

**I. Personal Data Controller**

The Controller of your personal data is **POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A. (POLISH CENTRE FOR TESTING AND CERTIFICATION),** 469 Puławska Street, 02-844 Warsaw, hereinafter referred to as **PCBC**.

**II. Data Protection Officer**

Dane kontaktowe Inspektora Ochrony Danych – adres do korespondencji: Inspektor Ochrony Danych, **POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.(POLISH CENTRE FOR TESTING AND CERTIFICATION),** ul. Puławska 469, 02-844 Warszawa; email: iod@pcbc.gov.pl.

Contact details of the Data Protection Officer – e-mail address: Data Protection Officer, **POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A. (POLISH CENTRE FOR TESTING AND CERTIFICATION),** 469 Puławska Street, 02-844 Warszawa; e-mail: iod@pcbc.gov.pl.

**III. Data processing purposes and grounds**

The Controller will process your data for the purposes of:

* if you are a Party to the Contract for management system certification (you are our client) your data will be processed to verify your identity as the Party to the Contract (Article 6 (1) (b) of GDPR,
* if you are a representative of our client mentioned in the comparison of the Contract for management system certification your data will be processed to determine and verify the entitlement to represent the entity (Article 6 (1) (f) of GDPR),
* if you are a person designated for contacts within the implementation of this contract and / or making ongoing arrangements within the cooperation of the Parties to the Contract your data will be processed to ensure proper performance of the Contract and ongoing contacts, to maintain cooperation between the Parties to the Contract (Article 6 (1) (f) of GDPR),
* if you are a person designated by our client mentioned in the comparison of the Contract for the management system certification to provide explanations within the audit carried out by the PCBC auditors your personal data will be processed to obtain contact enabling the determination of the date the meeting and after completion of the audit and preparation of the report, your data will be an evidence of conducting audit interviews with you (Article 6 (1) (f) of GDPR),
* possible determination, investigation or defence of claims related to business activity conducted by the PCBC (Article 6 (1) (f) of GDPR).

**IV. Categories of personal data**

The Controller will process your personal data only to the extent strictly defined and necessary, respectively to the aforementioned purposes. The Controller will not collect and process any redundant data except the data necessary to establish the correct right to represent the contracting Party and/or the business data for the correct execution of the Contract, ongoing communication and scheduling audit meetings with our auditors.

**V. Data storage period**

Your personal data will be stored for the period of performance of the Contract between the PCBC and our client mentioned in the comparison of the Contract for management system certification, in accordance with the law and for the period of pursuing potential claims between the Parties to the Contract.

**VI. Data subjects' rights**

You have the right of access to your data and the right to: rectify, restrict of processing, the right to object and the right to request erasure of data. Detailed principles of exercising the aforementioned rights are regulated in Articles 15-18 of GDPR.

If you are our client you have also the right to transmit your data provided do a Controller that means that you have the right to receive personal data concerning you in a structured, commonly used, machine-readable format and you have the right to transmit it to another controller without hindrance (Article 20 of GDPR).

**VII. Right to lodge a complaint to a supervisory authority**

You have the right to lodge a complaint to the supervisory authority, i.e. the President of the Office for Personal Data Protection in Poland.

**VIII. Recipients of the data**

Your personal data may be disclosed to entities authorized by law, e.g. control and supervisory authorities.

Your personal data may also be disclosed to processing entities in connection with the performance of contracts concluded by the PCBC under which they have been entrusted with personal data processing, including e.g.: IT service providers, companies providing legal services.

**IX. Source of data**

Your personal data has been provided to the PCBC by our client named in the comparison of the Contract for management system certification.

**X. Information concerning automated processing of personal data, including profiling**

Your data will not be processed by automated means, including profiling.

1. To be completed by the PCBC [↑](#footnote-ref-1)
2. Provision to be applied according to the form of concluding the Agreement [↑](#footnote-ref-2)