# PARTICIPATION DOCUMENTATION



Public procurement procedure no. SG-547

Budapest, 21 July 2010



# Basic information on the procedure:

# Subject of the procedure:

Purchase of immunochemical agents suitable for the detection of occult blood in human faeces and the relevant accessories

# Type of procedure:

Accelerated restricted public procurement procedure in a value reaching the Community limit

# **Contracting entity:**

Name: National Office of the Chief Medical Officer for Public Health

Address: 1097 Budapest, Gyáli út 2-6.

Telephone number: +36-1/476-1100/6424
Fax number: +36-1/476-6437

E-mail address: budai.andras@oth.antsz.hu; gazdig@oth.antsz.hu,

kovats.peter@oth.antsz.hu

Contact person: Dr. Budai András National Screening Co-ordinator

(hereinafter referred to as: **Contracting Entity**)

# Agent commissioned to administer the procedure:

Name: **S&G Consulting Kft.** 

Address: 1063 Budapest, Szinyei Merse u. 8. III./10.

Telephone number: +36-1/302-1280
Fax number: +36-1/269-2174
E-mail address: pap.laszlo@s-g.hu

Contact person: Pap László

(hereinafter referred to as: Agent)

# Identification codes of the procedure:

SG-547.

2010/S 139-214048 (21 July 2010)

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# I. Invitation to Participate

# II. Detailed participation criteria

# a) General information

This public procurement procedure shall be carried out in compliance with Act CXXIX of 2003 on Public Procurement (hereinafter: Kbt.).

Candidate Tenderers shall submit their Application for Participation in a manner that it is in full compliance with the form and content criteria set forth in the Kbt., the Invitation to Participate and this document, and shall attach the prescribed mandatory documents and declarations (hereinafter jointly referred to as: annexes).

If this documentation prescribes the use of a document template, then the relevant document template in the Document Templates section shall be used and attached to the Application for Participation, appropriately completed. A document template can be replaced by another document fully corresponding to the original in terms of content (e.g. in the case of references).

The Candidate Tenderer shall be liable for the veracity of the data provided and the declarations made in the Application for Participation, and that of the certificates and documents attached.

In order to facilitate preparation of the application to participate, the Contracting Entity shall also send, via e-mail, the document templates to those who purchase the Participation Documentation with the proviso, however, that the content of the printed documents shall apply in the first place, and that the Contracting Entity shall bear no liability for any loss arising from damages to electronic documents. At the Candidate Tenderer's separate request (e.g. in the absence of an e-mail address or in the event that it fails to function properly), the Contracting Entity shall also place the electronic documents at Candidate Tenderer's disposal on a CD.

As this documentation does not contain all the information included in the Invitation to Participate, we wish to emphasise that the Participation Documentation and the Invitation to Participate must be treated jointly. In the case of any inconsistency between the provisions of the Invitation to Participate and those of the documentation, the provisions of the Invitation to Participate shall apply. Of the paper-based and electronic versions of the documentation, the paper-based version shall apply.

The Candidate Tenderer's obligations shall include – following a careful study of the Invitation to Participate and this Participation Documentation – adherence to all the requirements, formal criteria and provisions therein, compliance with the specifications pertaining to the object of the procurement and consideration of the Contracting Entity's replies to requests for additional (explanatory) information.

Candidate Tenderer shall check the accuracy of all the information provided in the Invitation to Participate and this Participation Documentation as well as the accuracy of the information provided by the Contracting Entity in connection with the performance.

All consequences that may arise from failure to act in connection with the preparation, compilation and submission of the Application for Participation as well as the obtaining of information required

for the Application for Participation shall be borne by the Candidate Tenderer. Following the submission of the Application for Participation, the Contracting Entity will not take into account any request for modification made by the Candidate Tenderer citing the lack of accurate information.

The possibility of requesting information detailed herein helps the Candidate Tenderer obtain accurate and clear information required for the Application for Participation.

Candidate Tenderers shall – in addition to complying with the applicable statutory regulations – prepare the Application for Participation in accordance with the Invitation to Participate, this Participation Documentation and the replies received by Candidate Tenderers to their requests for additional (explanatory) information. It shall be a risk borne by the Candidate Tenderer and it shall entail the rejection of the tender if the Candidate Tenderer submits an erroneous or incomplete Application for Participation or submits an Application for Participation that does not comply, in terms of content and/or form, with the criteria specified in the Invitation to Participate, this Participation Documentation, the replies received by the Candidate Tenderers to their questions and the applicable statutory regulations, or if the Candidate Tenderer fails to rectify such deficiencies by way of corrections.

The services offered and to be performed shall fully comply with the specifications. In the detailed technical specifications, in some cases, references are made to producers, procedures, activities, persons, patents, trademarks and objects of a specific make, origin or type and brand names are used, pursuant to Sub-section 7, Section 58 of the Kbt., solely for the purpose of providing a description of the subject-matter of the contract that is sufficiently precise and intelligible. Services of 'equivalent value' can also be offered in the tenders.

Providing false or erroneous data will lead to the rejection of the Application for Participation, and its exclusion from the evaluation the Applications for Participation.

The information disclosed in the Application for Participation will be used exclusively for the establishment of the result of the public procurement procedure.

Candidate Tenderers shall treat this Participation Documentation confidentially and use it only within the framework of this procedure.

1. Major dates related to the procedure are contained in the Invitation to Participate. The calculation of deadlines shall be governed by the provisions of Section 15 of the Kbt. All deadlines specified in the Invitation to Participate – including the deadline for the submission of the Applications for Participation – shall be in Central European times (CET).

#### 2. Definitions

**Subcontractor:** shall mean a body or person who, on behalf of the Tenderer, participates directly in the performance of the contract awarded following the public procurement procedure.

**Certified copy:** shall mean the copy of a document made by or in the presence of a notary public, who shall certify the equivalence of said copy with the original by countersigning it.

**Corporate signature:** Having regard to Sub-section 1, Section 9 of Act V of 2006 on Public Company Information, Company Registration and Winding-up Proceedings, authorised signatories shall sign on behalf of the company in the same manner as executed on the authentic statement of signature (signature registration certificate witnessed and executed by a notary public).

#### 3. Funding, permission for the conclusion of the contract

Contracting Entity hereby declares that it has the powers to conclude the contract, and that it possesses the requisite funds in respect of the date of performance.

#### 4. Business secret

Candidate Tenderer may, expressly and in a separate annex, forbid the disclosure of the business secret it has disclosed in its Application for Participation. Candidate Tenderer may not forbid the disclosure of its name or address or any fact, information, solution or data that is taken into consideration in the course of the evaluation of its Application for Participation, or which is subject to the data reporting and information providing obligation specified in separate statutory regulations governing the disclosure of information of public interest. The provision of the contract concluded on the basis of the public procurement procedure which excludes assignment shall not qualify as a business secret.

## 5. Applicable law

Issues not regulated herein and those that are regulated, but not to a satisfactory extent, shall be governed by the applicable effective Hungarian law, in particular, the provisions of Act CXXIX of 2003.

6. During the participation phase the Contracting Entity may not request and the Candidate Tenderer may not submit a bid (§100 (2) of the Kbt.).

# b) Preparation of the Application for Participation

## 1. Supplementary documentation, information

The option open to Candidate Tenderers to request supplementary (explanatory) information is for the purposes of interpreting and clarifying the stipulations in the Invitation to Participate and this Participation Documentation. However, the answers of the Contracting Entity shall not entail the modification of the provisions of the Invitation to Participate or this Participation Documentation.

Candidate Tenderers may, not later than on the 8<sup>th</sup> day preceding the final deadline for submission of the Applications for Participation, request, in writing, additional information in respect of any information required for the preparation of the Application for Participation at the address, telefax number or e-mail address specified in the Invitation to Participate (Sub-section 1, Section 103 of the Kbt.).

The Contracting Entity shall make available the additional information before the 4<sup>th</sup> day preceding the final deadline for the submission of Applications for Participation. The contents of such information shall be made available to all Candidate Tenderers. The Contracting Entity shall fulfil said obligation by sending – by said deadline – the additional information to the address of the Candidate Tenderers whose identity has become known as a result of the purchase of the Participation Documents. Along with the Participation Documentation purchased at subsequent dates, the supplementary information shall also be provided to Candidate Tenderers. (Sections 2 and 3 of the Kbt.)

Candidate Tenderers shall prepare and submit their Application for Participation with due consideration of all the additional (explanatory) information provided.

#### 2. Modification or withdrawal of the Invitation to Participate and/or Participation Document

The Contracting Entity may, at any time prior to the expiry of the deadline open for the submission of the Applications for Participation, modify the conditions laid down in the invitation to Participate or the Participation Documentation. A notice indicating the new deadline for the submission of Applications for Participation shall be published with respect to the revised terms and conditions. (Sub-section 1, Section 76 of the Kbt.) The Contracting Entity shall send notification of the modification to the Candidate Tenderers whose identity became known prior thereto.

The Contracting Entity may, at any time prior to the expiry of the deadline open for the submission of the Applications for Participation, withdraw the Invitation to Participate. A notice with respect to the withdrawal of the Invitation to Participate shall be published. The Contracting Entity shall send notification of the withdrawal to the Candidate Tenderers whose identity became known prior to the cancellation. (Sub-section 2, Section 76 of the Kbt.)

#### 3. Modification and withdrawal of Applications for Participation

The Candidate Tenderer may, prior to the expiry of the deadline for the submission of the Applications for Participation, by way of a written declaration to the Contracting Entity – modify its Application for Participation. (Sub-section 1, Section 77 of the Kbt.) The modification shall be prepared and submitted in accordance with the formal criteria identical with those applicable to

the preparation of the original Application for Participation. Modification may be made in the form of a completely new Application for Participation, or it may be limited to those parts of the Application for Participation that are to be modified. In the latter case, the parts to be modified must be clearly identifiable clearly (e.g. by way of references to pages or chapters).

Pursuant to Sub-section 2, Section 77 of the Kbt., Applications for Participation may not be modified after the final deadline for submission – which is also the date of the public opening of the Applications for Participation – even with the consent of the Contracting Entity.

The Candidate Tenderer may, prior to the expiry of the deadline for the submission of the Applications for Participation, by way of a written declaration to the Contracting Entity – withdraw its Application for Participation.

## 4. Costs of the preparation of the Application for Participation

All costs incurred by the preparation and submission of the Application for Participation shall be borne by the Candidate Tenderer, and the Contracting Entity shall not, in any way, be made liable for said costs.

The Candidate Tenderer shall not claim the reimbursement of the costs it incurred in connection with the Application for Participation – with the exception of the cases specified in Sub-section 6, Section 54 and Section 351 of the Kbt. – from the Contracting Entity. The Contracting Entity shall not reimburse the Candidate Tenderer for any costs that the latter may incur in connection with a visit to or the inspection of the site or the preparation of the Application for Participation. No fee may be charged for the preparation of the Application for Participation.

Pursuant to Sub-section 5, Section 102 of the Kbt., the Contracting Entity shall reimburse the price of the Tender Documents if

- a) the Contracting Entity withdraws the Invitation to Participate;
- b) the participation phase of the procedure is deemed inconclusive under Paragraph c) or f) of Sub-section 1 of Section 115,
- c) the Contracting Entity fails to publicly announce the result of the participation phase before the date of the announcement of the results indicated in the Invitation to Participate or the modified date of the announcement of the results:
- d) the Contracting Entity fails to send the Tender Notice within five working days from the announcement of the results.

## 5. Language of the Application for Participation

The language of the Applications for Participation shall be the Hungarian language.

In the case of documents drawn up in a language other than Hungarian, the Contracting Entity shall accept translations made by any translation agency.

The Contracting Entity shall also accept data on the product's technical specifications and test results as well as user manuals and handling instructions in English.

#### 6. Grounds for exclusion

Pursuant to Sub-section1, Section 60 of the Kbt., the Candidate Tenderer, subcontractor or supplier of resources shall be excluded from participation in the procurement procedure who

- a) is being wound up, or is under bankruptcy or liquidation proceeding, or if the Tenderer (subcontractor) is adjudicated in a similar proceeding under national laws, or who is any similar situation arising from a similar procedure under national laws and regulations;
- b) has suspended its activities or whose operations have been suspended;
- c) has been convicted of a criminal offense with respect to its economic or professional conduct by a final judgment with no right of appeal, until exonerated from the detrimental consequences of having a criminal record; or whose activities are restrained for any period by a final court verdict pursuant to Paragraph b) or g) of Subsection (2) of Section 5 of Act CIV of 2001 on Criminal Sanctions in Connection with the Criminal Liability of Legal Persons, or if the Tenderer's operations are restrained by a final court order for similar reasons;
- d) has been excluded for any period from participating in public procurement procedures, during the period of such exclusion;
- e) has not fulfilled obligations with respect to the payment of taxes, customs duties or social security contributions for over a year in accordance with the legal provisions of the country in which it is established or with those of the country of the Contracting Entity, unless deferred payment has been authorised;
- f) has been found guilty of serious misrepresentation in supplying false information in a public procurement procedure that has been concluded within three years, and was excluded from the procedure in consequence, until the end of the period specified in the final and binding decision:
- g) has been found guilty by a final administrative or court ruling adopted within the preceding two years and sanctioned by employment penalty or default penalty under the Act on the Rules of Taxation for any infringement specified in Paragraph a) of Subsection (5) of Section 15 of Act XXXVIII of 1992 on Public Finances (hereinafter referred to as "PFA");
- h) has committed any criminal act in affiliation with organized crime by definition of the Criminal Code, or has been engaged in bribery or bribery in international relations, in any violation of the financial interest of the European communities, or involved in money laundering operations, or any crime of similar nature under the laws of his/her home country, if found guilty of such crime by a final court verdict with no right of appeal, until exonerated from the detrimental consequences of having a criminal record.

Pursuant to Sub-section 1, Section 61 of the Kbt., any Candidate Tenderer or any subcontractor to be contracted in an amount in excess of ten per cent of the total value of the contract, or any supplier of resources, or any subcontractor under Paragraph d), shall be excluded from participation in the procurement procedure that

- a) has been convicted of a misdemeanour offense concerning its economic or professional conduct by a final judgment made within five years to date, with no right of appeal;
- b) has been found guilty and sanctioned within the preceding five years of a legal offense committed in a public award procedure by final and executable decision of the Economic Competition Authority under Section 11 of the UMPA (Unfair Market Practices Act) or under Article 81 of the Treaty establishing the European Community, or by final executable court ruling passed in conclusion of the judicial review of the said decision of the Economic Competition Authority; or if the Candidate Tenderer has been condemned for a similar misdemeanour offense by another competition authority or court within the preceding five years:
- c) has been sanctioned by a final administrative or court ruling for any breach of obligation in connection with a public procurement contract within the preceding five years;
- d) is not registered in the country where established.

Pursuant to Sub-section 1, Section 62 of the Kbt., the Contracting Entity shall exclude from participation in the procurement procedure any Candidate Tenderer who - or in the case referred to in Paragraph b) of Sub-section 1 of Section 71 - whose subcontractor proposed to be contracted in a value in excess of ten per cent of the total value of the contract or whose supplier of resources:

- a) has been guilty of criminal negligence or grave professional misconduct within the preceding three years, or has been involved in any serious breach of obligation in connection with a public procurement contract within the preceding three years, as proven by any means which the authorities awarding contracts can justify;
- b) has been found guilty of serious misrepresentation in supplying false information in the public procurement procedure in violation of the provisions on disclosures [Sub-section 4 of Section 70, Section 71].

Manner in which grounds for exclusion are substantiated:

The Candidate Tenderer shall

- a), in writing, in the Application for Participation, make a declaration to the effect that neither it, nor the subcontractor under Paragraphs b) and c) of Sub-section 1 of Section 105 of the Kbt. that it has named, nor the supplier of resources falls under Sub-section 1 of Section 60 or Sub-section 1 of Section 61, for which it has the right to provide evidence;
- b) the Candidate Tenderer (or, in the case of a joint Application for Participation, Candidate Tenderers), the subcontractor under Paragraphs b) and c) of Sub-section 1 of Section 105 of the Kbt. that it has named and the supplier of resources shall, within 15 days from the date of the announcement of the results under Sub-section 1 of Section 117 of the Kbt., provide evidence in accordance with Sub-sections 2 to 5 of Section 63 and Sub-section 1 of 63/A of the Kbt. that it does not fall under Sub-section 1 of Section 60 or Sub-section 1 of Section 61 unless it provided such evidence in the Application for Participation.

#### 7. Rules governing the contracting of suppliers of resources

The circumstances under the following provisions of Kbt. shall not qualify as resources, therefore, no supplier of resources can be involved to prove them:

- Paragraph a) of Sub-section 1 of Section 66 of the Kbt. (statements issued by financial institutions, or evidence of relevant professional risk indemnity (liability) insurance)
- Paragraph b) of Sub-section 1 of Section 66 of the Kbt. (submission of financial statements under the relevant accounting laws)
- Paragraph c) of Sub-section 1 of Section 66 of the Kbt. (statement of the Tenderer's overall turnover and its turnover in respect of the services to which the contract relates)
- Paragraph a) of Sub-section 1 of Section 67 of the Kbt. (references)
- Paragraph d) of Sub-section 1 of Section 67 of the Kbt. (samples, description and/or photographs of the products to be supplied)
- Paragraph e) of Sub-section 1 of Section 67 of the Kbt. (certificates attesting conformity with product specifications or standards)
- Paragraph f) of Sub-section 1 of Section 67 of the Kbt. (quality control measures) unless majority control under the Hungarian Civil Code exists in respect of the Candidate Tenderer and the supplier of resources.

#### 8. Deadline for the submission of the applications for participation

Applications for Participation shall be submitted by mail only if sent with acknowledgement of receipt. Any risk arising from a delay in postal delivery shall be borne by the Candidate Tenderer.

The Contracting Entity shall confirm the receipt of an Application for Participation submitted in person by issuing an acknowledgement of receipt on site. The Contracting Entity shall refuse to accept applications submitted in open or damaged envelopes.

The fact of submission shall be the actual delivery of the consignment, which is the date indicated on the acknowledgement of receipt form or the return receipt form.

Applications for Participation shall be submitted by 10:00 a.m. on 27 July 2010, to the following address:

National Office of the Chief Medical Officer for Public Health 1097 Budapest, Gyáli út 2-6. Building D, Floor I, Unit C (Attention: Dr. Budai András, National Screening Co-ordinator)

Pursuant to Sub-section 1 of Section 75 of the Kbt., the Contracting Entity may extend the final deadline for the submission of Applications for Participation on one occasion citing the reason therefor. The Contracting Entity shall, prior to the expiry of the original deadline, publish the extension of said deadline in a public notice.

## 9. Late Applications for Participation

The Contracting Entity shall declare all Applications for Participation that it receives beyond the deadline that it has set for the submission of Applications for Participation invalid.

# 10. Opening of the Applications for Participation

The Contracting Entity shall start the opening of the Applications for Participation at the place and at the date indicated in the Invitation to Participate.

The Contracting Entity shall establish the expiry of the deadline for the submission of the Applications for Participation and the starting time for the opening procedure in accordance with the actual time provided by Magyar Telekom Nyrt. via telephone by dialling number 180.

The opening procedure shall last until all the Applications for Participation submitted until the expiry of the deadline for the submission of the Applications for Participation are opened.

The opening procedure may be attended by members of the committee commissioned by the Contracting Entity, the representatives of the tenderers, the persons whom they have invited, members of the Council of Public Procurements, the persons whom they have commissioned as well as the persons authorised to be in attendance by the applicable law. (Sub-section 2, Section 110 of the Kbt.)

The opening of the Applications for Participation shall, in the presence of the representatives of the Candidate Tenderers, commence upon the expiry of the deadline for the submission of the Applications for Participation. Candidate Tenderers shall not be given separate notification of the date of the opening. To provide evidence of their attendance, the Candidate Tenderers' representatives in attendance shall sign an attendance sheet.

When the Applications for Participation are opened, the Candidate Tenderers' name and address (registered seat, place of residence) as indicated in the original copy of the individual Applications for Participation and any modification or the withdrawal of the Application for Participation shall be read out.

The Contracting Entity shall prepare minutes on the opening of the Applications for Participation, any significant event during the opening procedure and all the legal representations made, which it shall send to the Candidate Tenderers within five days.

#### 11. A detailed review and evaluation of the Applications for Participation

Following the opening of the Applications for Participation, the persons commissioned by the Contracting Entity shall examine the said in detail and check, item by item, the documents submitted with respect to form and content. During the itemised check of the Applications for Participation, any circumstances giving rise to the invalidation of the Applications for Participation or the exclusion of the Candidate Tenderer shall be identified. Towards this end, a review of the Applications for Participation, primarily from a content-related perspective, shall also be performed.

The Contracting Entity provides the opportunity for statements and certificates and other documents found to be missing in the course of the detailed examination of the Applications for Participation and specified in Sub-section 2 of Section 112 of the Kbt., to be subsequently attached, their incompleteness to be rectified and any formal deficiencies with respect to the Applications for Participation to be remedied.

The opportunity to rectify deficiencies is available in respect of all documents.

The Contracting Entity shall inform all the Candidate Tenderers simultaneously, directly and in writing about the rectification of deficiencies, specifying the deadlines and the deficiencies for each application. Candidate Tenderers shall not be permitted to install in the process of the rectification of the deficiencies new offers jointly with other candidate tenderers or with the involvement of a subcontractor or a supplier of resources, including the relevant documents.

If the documents submitted as part of the rectification of deficiencies contain components not affected by the remedy process, and there are discrepancies between said documents and the original Application for Participation, the Contracting Entity shall regard the original Application for Participation as prevailing.

In order to facilitate the examination, evaluation and comparison of Applications for Participation and in order to clarify the meaning of unclear statements, declarations and certificates relating to documents concerning grounds for exclusion and eligibility, as well as other documents prescribed in the Invitation to Participate or in the Participation Documents, the Contracting Entity may request any one of the Candidate Tenderers, while simultaneously notifying the other Candidate Tenderers, to clarify their Application for Participation or to provide the necessary information. Requests for clarification and any additional information provided shall be in writing. Clarification shall not entail the modification of the Application for Participation. (Section 113 of the Kbt.)

The Contracting Entity shall – as a result of the detailed examination of the Applications for Participation and in accordance with the stipulations of the Invitation to Participate, the Participation Documentation and the Kbt. – identify the Applications for Participation that are invalid and Candidate Tenderers who will have to be excluded from the procedure.

#### 12. Invalidity of the Application for Participation

The invalidity of the Applications for Participation shall be established with reference to Paragraphs a)-f) of Sub-section 1 of Section 114 of the Kbt. as legal grounds; the Contracting Entity shall decide on the exclusion of the Candidate Tenderer in accordance with Sub-sections 2 and 3 of Section 114 of the Kbt.

Pursuant to Sub-section 1 of Section 114 of the Kbt., an Application for Participation shall be rejected if:

- a) it was submitted later than the final deadline for the submission of requests to participate as specified in the Invitation to Participate;
- b) the Candidate Tender presents a bid (Sub-section 2 of Section 100 of the Kbt.)
- c) the Candidate Tenderer or its subcontractor fails to comply with the provisions concerning conflict of interest (Section 10 of the Kbt.);
- d) the Candidate Tenderer, or its subcontractor, has been excluded from the procedure;
- e) the Candidate Tenderer or its subcontractor proposed to be contracted in a value in excess of ten per cent of the total value of the contract failed to meet the requirements for competence prescribed for contract performance;
- f) it fails to conform with the terms and conditions defined in the Invitation to Participate or in the Participation Documents, or the applicable statutory regulations in any other way.

Based on Sub-section 2 of Section 114 of the Kbt., the Contracting Entity shall exclude from the procedure the Candidate Tenderer (or its subcontractor):

- a) who has submitted an Application for Participation in spite of being subject to the grounds for exclusion (Sections 60-61);
- b) in respect of whom a reason for exclusion has arisen in the course of the procedure (Sections 60-62).

Based on Sub-section 3 of Section 114 of the Kbt., the Contracting Entity may exclude the Candidate Tenderer which need not be granted national treatment (Sub-section 4 of Section 1 of the Kbt.).

The Contracting Entity shall, within five days from the date of the decision on invalidity, while indicating the underlying reason for its decision, notify, in writing, the Candidate Tenderer whom it has excluded from the procedure or declared as ineligible for the performance of the contract or whose Application for Participation it has declared invalid.

## 13. Results of the participation phase

Pursuant to Section 115 of the Kbt., the participation phase shall be deemed inconclusive, if

- a) no Application for Participation was received;
- b) all received Applications for Participation were rejected for reasons of invalidity;
- c) the Contracting Entity declares the procedure inconclusive due to its being unable to conclude or fulfil the contract [Sub-section 4 of Section 111];

- d) the Contracting Entity decides to cancel the procedure due to the conduct of one of the Candidate Tenderers gravely violating the fairness of the procedure or the interests of other Candidate Tenderers:
- f) the Public Procurement Arbitration Committee overrules all of the Contracting Entity's decisions, and the Contracting Entity decides to launch a new procurement procedure or to cancel the procedure altogether.

Pursuant to Section 115/A of the Kbt.,

- (2) the Contracting Entity shall declare the procedure inconclusive if only one Application for Participation has been submitted, even if the Application for Participation were otherwise accepted;
- (3) the participation phase and the procedure shall be deemed inconclusive, if all but one Application for Participation received have been rejected;
- (4) the procedure shall not be declared inconclusive according to Section 115 of the Kbt., if the previous procedure of the same Contracting Entity was also inconclusive under this Section, and the Contracting Entity opened the procedure for the same object without making any changes to the Invitation to Participate and the Participation Documents.

#### 14. Announcement of the results of the participation phase

The Contracting Entity shall invite the Candidate Tenderers to the announcement of the decision on the award of the contract by way of this Participation Documentation, while sending the persons specified in the applicable statutory regulations a separate invitation indicating the date specified in the Invitation to Participate.

The Contracting Entity shall, in accordance with Sub-section 2 of Section 116 of the Kbt., draw up a written report on the Applications for Participation received, which, pursuant to Sub-section 1 of Section 118 of the Kbt., it shall disclose and hand over to the Candidate Tenderers in attendance at the announcement of the results and send to Candidate Tenderers who are absent via fax or e-mail on the day of and immediately following the announcement of the results.

Based on Sub-section 2 of Section 117 of the Kbt., the Contracting Entity may, if justified, postpone the date scheduled for the announcement of results once by no more than thirty days. In this case the contracting entity shall notify all Candidate Tenderers directly, in writing, at the same time prior to the expiry of the original deadline regarding the postponement and the reasons.

Pursuant to Sub-section 3 of Section 117 of the Kbt., the Contracting Entity may announce the results – if there is a valid reason therefor – sooner than the date indicated in the Invitation to Participate, of which it shall notify all Candidate Tenderers directly, in writing, at the same time at least 2 working days prior to the date as brought forward, citing the reasons therefor.

# c) Formal criteria for Applications for Participation

# 1. Form and signing of the Application for Participation

The original version and two photocopied versions of Applications for Participation (along with the annexes) shall be submitted separately in a sealed envelope. If there is any discrepancy between the original version and the photocopied versions, the contents of the original shall prevail.

The Candidate Tenderers shall place the original and each of the photocopied versions of the Application for Participation in a separate inner envelope, then all the copies in one outer envelope (box or package), which is then sealed. Each inner envelope shall clearly indicate whether the document inside is the "eredeti" ("original") or the "másolat" ("copy"). The outer envelope (box or package) shall clearly bear the designation and code number of the procedure as follows:

# Public procurement procedure no. SG-547

Purchase of immunochemical agents suitable for the detection of occult blood in human faeces and the relevant accessories

# Not to be opened before the deadline for submission of Applications for Participation (10:00 hrs 27 July 2010)!

The outer envelope must also bear the Candidate Tenderer's registered company name and central office, or if one of the Candidate Tenderer's organisational units proceeds in this public procurement procedure, then the premises or branch of such organisational unit.

If the copies of the Applications for Participation fail to bear the word 'original' or 'copy', then the Contracting Entity shall regard the copy first removed from the packaging during the opening procedure as original.

The Application for Participation shall be submitted in sealed packaging. The packaging shall qualify as not sealed if any one copy of the Application for Participation can be removed from it without the packaging damaged.

The copies of the Application for Participation shall be submitted typed, printed out on a computer or in indelible ink. Each page of the Application for Participation and the annexes thereto shall be furnished with continuous numbering. The declarations shall be signed by the person or persons signing the Application for Participation in their own hand in compliance with the requirements of corporate signing.

Any insertion, supplementation, deletion, writing-over and any change affecting the original text in any way and to any extent (hereinafter jointly: Correction) shall be validly made only if the original bears the original initials of the person or persons signing the Application for Participation next to the Correction. In the event that any correction is made, the erroneous text shall be crossed out (the use of correction fluid or corrective stickers is not allowed), and the person making the correction shall indicate the fact and date of the Correction next to the corrected text.

Copies of the Application for Participation shall be submitted in damage-proof binding guaranteeing their integrity, i.e. that no sheet can be removed from or inserted in the Application

for Participation without the physical integrity of the tender offer being damaged. (Based on this, wire-stitching or using binders/folders is acceptable only if the sheets are fixed firmly in place by means of further methods of fastening, e.g. a piece of string has been threaded through the sheets with the two loose ends of the string attached firmly to the side of the sheets in a manner that they cannot come apart without being damaged (e.g. they are fixed with a sticker which is stamped).)

# d) Content criteria for Applications for Participation

The Candidate Tenderer shall, in its Application for Participation, have the documents listed in the table below if, based on this participation Documentation, the given declaration, certificate or other documents pertain/s to the Candidate Tenderer, its subcontractor proposed to be contracted for a value in excess of 10% of the value of the contract, or any supplier of resources to the Candidate Tenderer. The documents in the Application for Participation shall comply with the content and formal criteria detailed in the table.

Please remember to make the declarations in accordance with the contents of the document templates provided in the Participation Documentation.

|                                                                             | T                     | o be submitted b                                    | у                           |                                 | -                                                                   |                                                     |
|-----------------------------------------------------------------------------|-----------------------|-----------------------------------------------------|-----------------------------|---------------------------------|---------------------------------------------------------------------|-----------------------------------------------------|
| Name of document                                                            | Candidate<br>Tenderer | Subcontractor<br>exceeding<br>10% of total<br>value | Supplier<br>of<br>resources | Content criteria                | Formal criteria                                                     | Misrepresentation<br>(Ss. 9/A, S. 4 of<br>the Kbt.) |
| Cover sheet                                                                 | Х                     | X                                                   | Х                           | As per the Document Template    |                                                                     |                                                     |
| Table of Contents                                                           | Х                     |                                                     |                             | Should contain page numbers     |                                                                     |                                                     |
| 1. General documents                                                        |                       |                                                     |                             |                                 |                                                                     |                                                     |
| Receipt verifying the purchase of the Tender Documentation                  | Х                     |                                                     |                             |                                 | An uncertified photocopy                                            |                                                     |
| Letter of authorisation (if appropriate)                                    | Х                     | Х                                                   | Х                           | As per the Document<br>Template | Original or certified copy To be furnished with corporate signature |                                                     |
| Co-operation declaration in the case of application for joint participation | Х                     |                                                     |                             |                                 | Original or certified copy To be furnished with corporate signature | Х                                                   |

|                                                          | To be submitted by    |                                                     |                             | 1                                                                                      |                                                                     |                                                     |
|----------------------------------------------------------|-----------------------|-----------------------------------------------------|-----------------------------|----------------------------------------------------------------------------------------|---------------------------------------------------------------------|-----------------------------------------------------|
| Name of document                                         | Candidate<br>Tenderer | Subcontractor<br>exceeding<br>10% of total<br>value | Supplier<br>of<br>resources | Content criteria                                                                       | Formal criteria                                                     | Misrepresentation<br>(Ss. 9/A, S. 4 of<br>the Kbt.) |
| Declaration pursuant to P. a), Ss. 1, S. 105 of the Kbt. | Х                     |                                                     |                             | As per the Document Template Declaration on the absence or "no" must also be enclosed. | Original or certified copy To be furnished with corporate signature | Х                                                   |
| Declaration pursuant to P. b), Ss. 1, S. 105 of the Kbt. | Х                     |                                                     |                             | As per the Document Template Declaration on the absence or "no" must also be enclosed. | Original or certified copy To be furnished with corporate signature | X                                                   |
| Declaration pursuant to P. c), Ss. 1, S. 105 of the Kbt. | Х                     |                                                     |                             | As per the Document Template Declaration on the absence or "no" must also be enclosed. | Original or certified copy To be furnished with corporate signature | X                                                   |
| Declaration pursuant to Ss. 3, S. 105 of the Kbt.        | Х                     |                                                     |                             | As per the Document<br>Template                                                        | Original or certified copy To be furnished with corporate signature | Х                                                   |
| Copyright declaration                                    | Х                     |                                                     |                             | As per the Document<br>Template                                                        | Original or certified copy To be furnished with corporate signature | Х                                                   |
| Conflict of interest declaration                         | Х                     | X                                                   | X                           | As per the Document<br>Template                                                        | Original or certified copy To be furnished with corporate signature | Х                                                   |

|                                                                                                                                 | To be submitted by    |                                                     |                             |                                                                                                |                                                                                                                                                                                                           |                                                     |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------|-----------------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Name of document                                                                                                                | Candidate<br>Tenderer | Subcontractor<br>exceeding<br>10% of total<br>value | Supplier<br>of<br>resources | Content criteria                                                                               | Formal criteria                                                                                                                                                                                           | Misrepresentation<br>(Ss. 9/A, S. 4 of<br>the Kbt.) |
| 2. Evidence for no grounds for exclusion                                                                                        |                       |                                                     |                             |                                                                                                |                                                                                                                                                                                                           | _                                                   |
| Statement regarding grounds for exclusion under Ss. 1, S. 60 and Ss.1, S. 61                                                    | Х                     | Х                                                   | Х                           | As per the Document<br>Template                                                                | Original or certified copy To be furnished with corporate signature                                                                                                                                       | Х                                                   |
| Certificate of incorporation                                                                                                    | Х                     | Х                                                   | Х                           |                                                                                                | Issued not earlier than 60 days prior to the deadline for the submission of Applications for Participation Original or certified copy                                                                     |                                                     |
| Clean criminal record (only in the case of private entrepreneurs)                                                               | Х                     | Х                                                   | Х                           |                                                                                                | Issued not earlier than 90 days prior to the deadline for the submission of Applications for Participation Original or certified copy                                                                     |                                                     |
| Business licence (only in the case of private entrepreneurs)                                                                    | Х                     | X                                                   | Х                           |                                                                                                | Certified copy                                                                                                                                                                                            |                                                     |
| A certificate issued by APEH (Hungarian Tax Authority) or the corresponding foreign tax authority and social security authority | X                     | X                                                   | Х                           | It must show that it has been issued "for the purpose of use in a public procurement process". | Issued not earlier than 1 year prior to the announcement of the results Original or certified copy  (the Candidate Tenderer may enclose the document within 15 days from the announcement of the results) |                                                     |

|                                                                                                                    | To be submitted by    |                                                     |                             |                                                                                                |                                                                                                                                                                                                           |                                                     |
|--------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------|-----------------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Name of document                                                                                                   | Candidate<br>Tenderer | Subcontractor<br>exceeding<br>10% of total<br>value | Supplier<br>of<br>resources | Content criteria                                                                               | Formal criteria                                                                                                                                                                                           | Misrepresentation<br>(Ss. 9/A, S. 4 of<br>the Kbt.) |
| Certificate issued by the<br>Hungarian Customs and Finance<br>Guard or the corresponding<br>foreign customs office | Х                     | X                                                   | Х                           | It must show that it has been issued "for the purpose of use in a public procurement process". | Issued not earlier than 1 year prior to the announcement of the results Original or certified copy  (the Candidate Tenderer may enclose the document within 15 days from the announcement of the results) |                                                     |
| 3. Data and facts supporting the Candidate Tenderer's eligibility                                                  |                       |                                                     |                             |                                                                                                |                                                                                                                                                                                                           |                                                     |
| 3./a. Financial and economic eligibility                                                                           |                       |                                                     |                             |                                                                                                |                                                                                                                                                                                                           |                                                     |
| Declaration on account-keeping financial institutions and bank accounts                                            | Х                     | X                                                   | Х                           | As per the Document Template Should indicate all bank accounts                                 | To be furnished with corporate signature                                                                                                                                                                  | Х                                                   |

|                                                                                                                               | T                     | o be submitted b                                    | у                           | *                                                                                                                                                                                                                                                                                                        |                                                                                                                                       |                                                     |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Name of document                                                                                                              | Candidate<br>Tenderer | Subcontractor<br>exceeding<br>10% of total<br>value | Supplier<br>of<br>resources | Content criteria                                                                                                                                                                                                                                                                                         | Formal criteria                                                                                                                       | Misrepresentation<br>(Ss. 9/A, S. 4 of<br>the Kbt.) |
| Certificate issued by the financial institution (if appropriate)                                                              | X                     | X                                                   | X                           | In respect of all bank accounts the following information:  • How long the given financial institution has been managing the Candidate Tenderer's bank account,  • Was there an instance of queuing for longer than 60 days in the year immediately preceding the date of the issue of this certificate? | Issued not earlier than 30 days prior to the deadline for the submission of Applications for Participation Original or certified copy |                                                     |
| Professional indemnity insurance                                                                                              | X                     | X                                                   | X                           | Insurance policy or an official declaration by the insurance company  Min. HUF 2 million p.a.  Min. HUF 1 million/loss event                                                                                                                                                                             | Original or certified copy                                                                                                            |                                                     |
| Declaration of commitment by suppliers of resources with regard to their financial and economic capabilities (if appropriate) |                       |                                                     | Х                           | As per the Document<br>Template                                                                                                                                                                                                                                                                          | To be furnished with corporate signature Original or certified copy Authenticated by notary public if appropriate                     | X                                                   |

|                                                                                                                                               | To be submitted by    |                                                     |                             |                                                                                                                                                                              |                                                                                        |                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|-----------------------------------------------------|
| Name of document                                                                                                                              | Candidate<br>Tenderer | Subcontractor<br>exceeding<br>10% of total<br>value | Supplier<br>of<br>resources | Content criteria                                                                                                                                                             | Formal criteria                                                                        | Misrepresentation<br>(Ss. 9/A, S. 4 of<br>the Kbt.) |
| Agreement between the supplier of resources and the Candidate Tenderer (if appropriate)                                                       | Х                     |                                                     | Х                           |                                                                                                                                                                              | To be furnished with corporate signature                                               |                                                     |
| 3./b. Technical and professional eligibility                                                                                                  |                       |                                                     |                             |                                                                                                                                                                              |                                                                                        |                                                     |
| Certification from certifying bodies                                                                                                          | Х                     | X                                                   | Х                           | ORKI, CE or equivalent quality assurance certificate                                                                                                                         | An uncertified photocopy                                                               |                                                     |
| Declaration of commitment by<br>suppliers of resources with<br>regard to their technical and<br>professional capabilities (if<br>appropriate) |                       |                                                     | Х                           | As per the Document<br>Template                                                                                                                                              | To be furnished with corporate signature Authenticated by notary public if appropriate |                                                     |
| Agreement between the supplier of resources and the Candidate Tenderer (if appropriate)                                                       | Х                     |                                                     | Х                           |                                                                                                                                                                              | To be furnished with corporate signature                                               |                                                     |
| 4. Other documents                                                                                                                            |                       |                                                     |                             |                                                                                                                                                                              |                                                                                        |                                                     |
| Specimen signature(s)                                                                                                                         | X                     | X                                                   | X                           | The signature specimen of the person duly authorised to sign for the company and signing the Application for Participation or granting authorisation for the signing thereof | Original or certified copy                                                             |                                                     |
| Confidentiality statement                                                                                                                     | Х                     | Х                                                   | Х                           | As per the Document Template                                                                                                                                                 | To be furnished with corporate signature                                               |                                                     |
| Business secret statement (if appropriate)                                                                                                    | Х                     |                                                     |                             | As per the Document Template                                                                                                                                                 | To be furnished with corporate signature                                               |                                                     |

|                                         | To be submitted by    |                                                     |                             |                  |                 |                                                     |
|-----------------------------------------|-----------------------|-----------------------------------------------------|-----------------------------|------------------|-----------------|-----------------------------------------------------|
| Name of document                        | Candidate<br>Tenderer | Subcontractor<br>exceeding<br>10% of total<br>value | Supplier<br>of<br>resources | Content criteria | Formal criteria | Misrepresentation<br>(Ss. 9/A, S. 4 of<br>the Kbt.) |
| Other documents intended to be attached | Х                     | X                                                   | X                           |                  |                 |                                                     |

# III. Specifications

## **Technical specifications**

The tasks to be carried out by the supplier in the course of delivery/performance and the duties whose fulfilment is required by contractual performance are set forth in the contractual terms and conditions laid down in Chapter IV of this documentation.

## **Objective**

Diagnostic procedure financed as a model programme by the Ministry of Health within the framework of the National Programme for Public Health, suitable for the public health screening of the population, aimed to detect occult blood in human faeces with the adoption of such a human haemoglobin-specific immunochemical method providing automated results that can be corroborated by strong and highly reliable scientific evidence and the diagnostic performance of which in respect of the screened population is good. The objective of this public procurement is, with a view to implementing the above, to purchase sample collection receptacles, chemical agents and – if the evaluation technology of the product bidden so requires – to secure the on-site installation of automated measuring equipment.

#### Quantity

Number of the tests intended to be conducted within the framework of the model programme over a 12-month period: 30,000 persons (+100%)

# **Specifications**

Criteria for the sample collection receptacle: It

- should provide for the possibility that samples at least in a number required by the sampling method can be collected,
- should be easy for patients to handle,
- should come with a guide for the patient.
- can be forwarded as consignment by post,
- should have an at least one-year shelf life period,
- should be CE labelled.

Analysis-related criteria for the test kit and the measuring equipment:

- the lowest threshold for the detectability of occult blood in faeces: min. 50 ng/ml or below,
- speed of analysis: at least 200 tests/hour,
- standard internal and external laboratory quality assurance procedures are available.
- product shelf life in respect of the chemical agents should in light of the annual number of tests be at least 12 months.
- The threshold value of the test prozone effect should be fixed.
- The test kit should comply with the European IVD directive and be CE labelled.
- The test kit should be able to signal the prozone effect.
- The automated measuring equipment should be suitable for producing quantitative results.

#### The bid should contain:

- 1. analysis-related and other performance indicators of the test,
- 2. indicators of the diagnostic capabilities of the test kit (e.g. sensitivity, specificity, predictive value, diagnostic cut-off value and ROC curve) in respect of the <u>screened</u> population; scientific evidence supporting data,
- 3. costs per test per patient, including the costs of one single test and other fast-moving materials as well as the costs of control tests and calibration needed for ensuring measuring reliability,
- 4. terms and conditions of insurance coverage for and maintenance under warranty of the measuring equipment.

Presenting a tender offer in the Application for Participation is forbidden.

# IV. Document templates

# **COVER SHEET**

| Number and object of the procedure:                   | SG-547. Purchase of immunochemical agents suitable for                      |
|-------------------------------------------------------|-----------------------------------------------------------------------------|
|                                                       | the detection of occult blood in human faeces and the relevant accessories. |
| Name of company applying for participation:           |                                                                             |
| Address:                                              |                                                                             |
| Telephone number:                                     |                                                                             |
| Fax number:                                           |                                                                             |
| E-mail address:                                       |                                                                             |
| Company registration number:                          |                                                                             |
| Court of Registration:                                |                                                                             |
| Statistical Code:                                     |                                                                             |
| Tax number:                                           |                                                                             |
| EU tax number:                                        |                                                                             |
| Classification under Kkvt. (Act on SMEs):             |                                                                             |
| Name of account-keeping bank and bank account number: |                                                                             |
| Name of contact person:                               |                                                                             |
| Mobile phone number of contact person:                |                                                                             |
| Fax number of contact person:                         |                                                                             |

The same particulars shall be provided with respect to the sub-contractors to be contracted in a value in excess of 10% of the total value of the contract (if the Candidate Tenderer intends to contract such sub-contractors).

# LETTER OF AUTHORISATION

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Procedure number: SG-547.

| blood in human faeces and the relevant accessories<br>Contracting Entity: National Office of the Chief Medi<br>Gyáli út 2-6.)                                                                                                                          |                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Company making the declaration  Name: Registered seat: Participating in the procedure as (Please delete as exceeding 10%/supplier of resources                                                                                                         | appropriate): Candidate Tenderer/sub-contractor                        |
| I, the undersignedfor the company making this declaration hereby aut employee of                                                                                                                                                                       | horise, an                                                             |
| <ul> <li>represent me in this public procurement procedure Application for Participation on my behalf,</li> <li>provide information, make legal representations and</li> <li>conclude the contract which the Tenderer, by signing</li> <li></li> </ul> | and sign the documents constituting part of the undertake commitments, |
| (*Please add/delete/clarify powers/competences as app                                                                                                                                                                                                  | ropriate.)                                                             |
| daymonth ye                                                                                                                                                                                                                                            | ar                                                                     |
| Authorising party Corporate Signature                                                                                                                                                                                                                  | Authorised party                                                       |
| Witnesses:                                                                                                                                                                                                                                             |                                                                        |
| 1. Name:                                                                                                                                                                                                                                               | Signature                                                              |
| Address:                                                                                                                                                                                                                                               |                                                                        |
|                                                                                                                                                                                                                                                        |                                                                        |

N.B.

In the case of joint participation, to be duly signed by all Candidate Tenderers.

2. Name: .....

Address: .....

If an authorised person proceeds with respect to the submission of the Application for Participation, the Letter of Authorisation is to be attached.

Signature .....

# Declaration based on Paragraph a), Sub-section 1, Section 105 of the Kbt.

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Procedure number: **SG-547.** 

blood in human faeces and the relevant accessories.

Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest, Gyáli út 2-6.) Company making the declaration • Name: ..... • Participating in the procedure as a Candidate Tenderer I, the undersigned ...... as the representative duly authorised to sign in the above public procurement procedure for the company making this declaration hereby declare that our company intends – in order to perform the contract to be concluded – to contract a sub-contractor in a value not exceeding 10% of the total value of the contract for the performance of the following activities and tranches of work: Description of public procurement activity/tranche of work: Please remember that if you do not intend to contract a sub-contractor in a value not exceeding 10% of the total value of the contract, a declaration on the absence of intention must be enclosed. ..... day ...month ... year

Corporate Signature

# Declaration based on Paragraph b), Sub-section 1, Section 105 of the Kbt.

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Procedure number: **SG-547.** 

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| n in the<br>that our<br>ng sub-<br>ance of |
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| t                                          |

# Declaration based on Paragraph c), Sub-section 1, Sub-section 105 of the Kbt.

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Procedure number: **SG-547.** 

|                       | es and the relevant accessories.<br>tional Office of the Chief Medical Officer f                          | or Public Health (1097 Budapest     |
|-----------------------|-----------------------------------------------------------------------------------------------------------|-------------------------------------|
| •                     |                                                                                                           |                                     |
| above public procurem | as the represent and procedure for the company making this corder to perform the contract to be concluded | leclaration hereby declare that our |
|                       | Supplier of resources:                                                                                    | Description of the resources        |
| Name                  | Registered place of business:                                                                             | to be supplied                      |
| the absence of intent | t if you do not intend to contract a supplicion must be enclosed,                                         | er of resources, a declaration on   |
|                       |                                                                                                           | Corporate Signature                 |

# Declaration based on Sub-section 3, Section 105 of the Kbt.

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Procedure number: **SG-547.** 

blood in human faeces and the relevant accessories.

| Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest, Gyáli út 2-6.) |
|-------------------------------------------------------------------------------------------------------------------|
| Company making the declaration  Name:                                                                             |
| I, the undersigned                                                                                                |
| daymonth year                                                                                                     |
| Cornorate Signature                                                                                               |

# **Declaration on copyrights**

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Procedure number: **SG-547.** 

blood in human faeces and the relevant accessories.

| Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest, Gyáli út 2-6.) |
|-------------------------------------------------------------------------------------------------------------------|
| Company making the declaration  Name:                                                                             |
| I, the undersigned                                                                                                |
| ,                                                                                                                 |
| Corporate Signature                                                                                               |

# **Declaration on conflict of interest**

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult blood in human faeces and the relevant accessories.

Procedure number: **SG-547**.

| Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest, Gyáli út 2-6.)                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Company making the declaration     Name:                                                                                                                                                                                                                                                                                                      |
| I, the undersigned                                                                                                                                                                                                                                                                                                                            |
| We acknowledge and agree that if, with respect to our company, its executive officers, employees and the relatives thereof, the existence of the conflict of interest under Section 10 of the Kbt. comes to the knowledge of the Contracting Entity, it shall have the right to exclude our Application for Participation from the procedure. |
| daymonth year                                                                                                                                                                                                                                                                                                                                 |
| Corporate Signature                                                                                                                                                                                                                                                                                                                           |

# Declaration on grounds for exclusion under Sub-section 1, Section 60 and Sub-section 1, Section 61 of the Kbt.

Procedure number: SG-547.

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult blood in human faeces and the relevant accessories.

Contracting Entity: **National Office of the Chief Medical Officer for Public Health** (1097 Budapest, Gyáli út 2-6.)

| Company making the declaration |
|--------------------------------|
|--------------------------------|

- Name: .....
- Registered seat: ......
- Participating in the procedure as (Please delete as appropriate): Candidate Tenderer/sub-contractor exceeding 10%/supplier of resources

Pursuant to Sub-section1, Section 60 of the Kbt., the Candidate Tenderer, subcontractor or supplier of resources shall be excluded from participation in the procurement procedure who

- a) is being wound up, or is under bankruptcy or liquidation proceeding, or if the Candidate Tenderer (subcontractor) is adjudicated in a similar proceeding under national laws, or who is any similar situation arising from a similar procedure under national laws and regulations:
- b) has suspended its activities or whose operations have been suspended;
- c) has been convicted of a criminal offense with respect to its economic or professional conduct by a final judgment with no right of appeal, until exonerated from the detrimental consequences of having a criminal record; or whose activities are restrained for any period by a final court verdict pursuant to Paragraph b) or g) of Subsection (2) of Section 5 of Act CIV of 2001 on Criminal Sanctions in Connection with the Criminal Liability of Legal Persons, or if the Candidate Tenderer's operations are restrained by a final court order for similar reasons;
- d) has been excluded for any period from participating in public procurement procedures, during the period of such exclusion:
- e) has not fulfilled obligations with respect to the payment of taxes, customs duties or social security contributions for over a year in accordance with the legal provisions of the country in which it is established or with those of the country of the Contracting Entity, unless deferred payment has been authorised:
- f) has been found guilty of serious misrepresentation in supplying false information in a public procurement procedure that has been concluded within three years, and was excluded from the procedure in consequence, until the end of the period specified in the final and binding decision;
- g) has been found guilty by a final administrative or court ruling adopted within the preceding two years and sanctioned by employment penalty or default penalty under the Act on the Rules of Taxation for any infringement specified in Paragraph a) of Subsection (5) of Section 15 of Act XXXVIII of 1992 on Public Finances (hereinafter referred to as "PFA");
- h) has committed any criminal act in affiliation with organized crime by definition of the Criminal Code, or has been engaged in bribery or bribery in international relations, in any violation of the financial interest of the European communities, or involved in money laundering operations, or any crime of similar nature under the laws of his/her home country, if found guilty of such crime by a final court verdict with no right of appeal, until exonerated from the detrimental consequences of having a criminal record.

Pursuant to Sub-section 1, Section 61 of the Kbt., any Candidate Tenderer or any subcontractor to be contracted in an amount in excess of ten per cent of the total value of the contract, or any supplier of resources, or any subcontractor under Paragraph d), shall be excluded from participation in the procurement procedure that

- a) has been convicted of a misdemeanour offense concerning its economic or professional conduct by a final judgment made within five years to date, with no right of appeal;
- b) has been found guilty and sanctioned within the preceding five years of a legal offense committed in a public award procedure by final and executable decision of the Economic Competition Authority under Section 11 of the UMPA (Unfair Market Practices Act) or under Article 81 of the Treaty establishing the European Community, or by final executable court ruling passed in conclusion of the judicial review of the said decision of the Economic Competition Authority; or if the Candidate Tenderer has been condemned for a similar misdemeanour offense by another competition authority or court within the preceding five years;
- c) has been sanctioned by a final administrative or court ruling for any breach of obligation in connection with a public procurement contract within the preceding five years;
- d) is not registered in the country where established.

| daymonth year |                     |
|---------------|---------------------|
|               |                     |
|               |                     |
|               |                     |
|               |                     |
|               | Corporate Signature |

# Declaration on account-keeping financial institutions and bank accounts

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Procedure number: **SG-547**.

| blood in human faeces and the relevant accessories.  Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest, Gyáli út 2-6.)                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Company making the declaration  Name:                                                                                                                                                          |
| <ul> <li>Registered seat:</li> <li>Participating in the procedure as (Please delete as appropriate): Candidate Tenderer/sub-contractor exceeding 10%/supplier of resources</li> </ul>          |
| I, the undersigned as the representative duly authorised to sign for the company making this declaration hereby declare that our company only holds the bank accounts listed below:            |
| 1.  Name of financial institution: Registered seat of financial institution: Company registration number of financial institution: Bank account number(s): Date of opening bank account:       |
| 2.  Name of financial institution: Registered seat of financial institution: Company registration number of financial institution: Bank account number(s): Date of opening bank account:       |
| 3. (etc.) Name of financial institution: Registered seat of financial institution: Company registration number of financial institution: Bank account number(s): Date of opening bank account: |
| daymonth year                                                                                                                                                                                  |
| Corporate Signature                                                                                                                                                                            |

# Declaration of commitment by suppliers of resources with respect to their financial and economic capabilities

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

blood in human faeces and the relevant accessories. Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest, Gyáli út 2-6.) Company making the declaration • Name: ..... Registered seat: ...... Participating in the procedure as supplier of resources I, the undersigned ...... as the representative duly authorised to sign for the company making this declaration hereby declare that we shall provide the financial and economic conditions specified in the Application for Participation submitted by required for the performance of the contract. I further declare that we have, at our disposal, the financial and economic resources required for the performance of the contract to be concluded on the basis of this public procurement procedure. The commitment pertains to the following financial and economic eligibility criteria: ..... I hereby declare that with respect to the company making the declaration and the Candidate Tenderer (Please underline as appropriate.)

majority control under the Civil Code exists.

..... day ...month ... year

Procedure number: SG-547.

• **no** majority control under the Civil Code exists, therefore, we hereby attach the agreement between our company and the Candidate Tenderer. (*In this case this declaration is to be notarised.*)

|  |  | Carparata Cianatura |  |
|--|--|---------------------|--|
|  |  | Corporate Signature |  |
|  |  |                     |  |

# Declaration of commitment by suppliers of resources with regard to their professional and technical capabilities

Procedure number: SG-547.

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult blood in human faeces and the relevant accessories. Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest, Gyáli út 2-6.) Company making the declaration • Name: ..... Registered seat: ...... Participating in the procedure as supplier of resources I, the undersigned ...... as the representative duly authorised to sign for the company making this declaration hereby declare that we shall provide the professional and technical conditions specified in the Application for Participation submitted by required for the performance of the contract. I further declare that we have, at our disposal, the professional and technical resources required for the performance of the contract to be concluded on the basis of this public procurement procedure. The commitment pertains to the following professional and technical eligibility criteria: I hereby declare that with respect to the company making the declaration and the Candidate Tenderer (Please underline as appropriate.) majority control under the Civil Code exists. **no** majority control under the Civil Code exists, therefore, we hereby attach the agreement between our company and the Candidate Tenderer. (In this case this declaration is to be notarised.)

Corporate Signature

..... day ...month ... year

# **Confidentiality statement**

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest,

Procedure number: **SG-547**.

blood in human faeces and the relevant accessories.

| Gyáli ú                                       | t 2-6.)                                                                                                                                                |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                               | ny making the declaration                                                                                                                              |
| <ul><li>Reg</li><li>Part</li></ul>            | gistered seat:tise: like in the procedure as (Please delete as appropriate): Candidate Tenderer/sub-contracto eeding 10%/supplier of resources         |
| above<br>verbal<br>connect<br>as Con<br>which | he undersigned                                                                                                                                         |
| 2.) The                                       | confidentiality obligation arising from this Statement shall not apply to the information that                                                         |
| a)                                            | is in the public domain or will enter the public domain at any time in the future without the Party making this statement being at fault for such, or  |
| b)                                            | was already known to the Party making this statement prior to the signing of this declaration, fo which evidence can be provided, or                   |
| c)                                            | was lawfully obtained by the Party making this declaration from a third party not bound by a confidentiality agreement with the Contracting Entity, or |
| d)                                            | whose disclosure is required by the rules of applicable legislation.                                                                                   |
| •                                             | confidentiality commitment described above shall cease in three (3) years from the date of the of this statement.                                      |
|                                               | ,                                                                                                                                                      |
|                                               | Corporate Signature                                                                                                                                    |

# **Business Secret Statement**

Subject of the procedure: Purchase of immunochemical agents suitable for the detection of occult

Procedure number: **SG-547**.

blood in human faeces and the relevant accessories.

| Contracting Entity: National Office of the Chief Medical Officer for Public Health (1097 Budapest, Gyáli út 2-6.) |
|-------------------------------------------------------------------------------------------------------------------|
| Company making the declaration  Name:                                                                             |
| I, the undersigned                                                                                                |
| daymonth year                                                                                                     |
| Corporate Signature                                                                                               |