

ANSWERS TO CLARIFICATION QUERIES APRIL 19TH, 2020

TENDER CALLING WITH SIMPLIFIED PROCEDURE AND OF MAXIMUM URGENCY REGARDING THE ACQUISITION OF KITS, REAGENTS, AND CONSUMABLES FOR THE PERFORMANCE OF 150.000 SEROLOGICAL TESTS AIMED AT OBTAINING A SAMPLE SURVEY ON THE DISSEMINATION OF THE SARS-COV-2 INFECTION

NUMERO	QUESITO	CHIARIMENTO
1	<p>We kindly ask to identify which are the reliability requisites required pursuant to article 4 paragraph 1 of the call.</p> <p>In particular, we kindly ask to clarify whether, in accordance to tender specification, it is required to demonstrate such requirements in a specific way (i.e. global turnover, bank references or any other technical requisites).</p>	<p>With reference to technical and economic capacity requirements, the competitor should refer to those set out by article 83 of Legislative decree no. 50/2016.</p> <p>Since the tender specification does not contain any specific provision about the way to demonstrate the compliance to such requirements, such demonstration can be given by any means.</p> <p>In particular, with reference to the economic capacity requirement, the above mentioned article 83, paragraph 5, provides that such a capacity shall not exceed twice the tender value. As a consequence, in this regard, the minimum annual turnover requirement to be compliant with is at least equal to the contract amount.</p> <p>Due to the specificity and the necessity of any possible simplification of this procedure, the compliance to the economic capacity requirements may be demonstrated in any way, but it could be better in a way set forth by article 86, paragraph 4, and the Attachment no. XVII, part 1[^] to the Legislative decree no. 50/2016.</p>
2	<p>We kindly ask if it is allowed to participate to the tender procedure as an agent for Italy.</p>	<p>In order to award the contract to a reliable company, competitors must be an national or foreign manufacturer of the medical devices requested by the tender notice.</p> <p>It is allowed to submit a bid to the call by an agent, only if such agent has been expressly authorized by the manufacturer company and the agent has been expressly allowed to represent the manufacturer during the tender procedure.</p> <p>Nevertheless, in addition of the agent's representation power, also the manufacturer compliance to technical and economic capacity requirements have to be demonstrate.</p>
3	<p>We require a clarification concerning the following minimum requirements:</p> <p>c) A test specificity not lower than 95%</p>	<p>To identify the meaning of "specificity" and "sensitivity", please refer to the definitions commonly used for the evaluation of diagnostic tests.</p>

English translation for convenience only

	d) A test sensitivity not lower than 90%	
4	We kindly ask if, in order to participate in the tender procedure, it is provided an application form. If yes, we kindly ask where we can download it.	Please refer to Article 5 of the call for tender (quote) “ 5. How to submit tenders: Tenders, accompanied by the required documentation, shall be sent, in PDF format, to the "Extraordinary Commissioner for COVID-19 emergency", exclusively by certified e-mail: commissarioemergenacovid19@pec.governo.it . The document containing the qualitative tender (description of products and their qualitative requirements as indicated sub 3)) and the one containing the economic offer must be signed by qualified electronic signature.” (unquote)
5	With regards to the call, even if we don't meet the technical requirements for serological kits set out by the tender notice, but we represent in Italy one of the world leading company of such industry, we kindly ask if we can participate to the tender procedure	<p>In order to award the contract to a reliable company, competitors must be an national or foreign manufacturer of the medical devices requested by the tender notice.</p> <p>It is allowed to submit a bid to the call by an agent, only if such agent has been expressly authorized by the manufacturer company and the agent has been expressly allowed to represent the manufacturer during the tender procedure. Nevertheless, in addition of the agent's representation power, also the manufacturer compliance to technical and economic capacity requirements have to be demonstrate.</p> <p>The tender specification is unequivocal as for the kind of the requested products. Anyway, at this stage of the procedure, since any exclusion from the tender procedure is up to the selection board and it is not possible to anticipate the latter's evaluations, the decision whether to participate or not to the tender is remitted to the company.</p>