

Appendix 4: European Single Procurement Document (ESPD)

Part I: Information concerning the procurement procedure and the contracting authority

Reference of the relevant notice ⁽¹⁾ published in the *Official Journal of the European Union*:

OJEU S number [Click here and insert details](#), date [Click here and insert date](#), page [Click here and insert page](#)

Notice number in the OJ S: [Click here and insert notice number](#)

If there is no call for competition in the OJEU, then the contracting authority or contracting entity must fill in the information allowing the procurement procedure to be unequivocally identified:

In case publication of a notice in the *Official Journal of the European Union* is not required, please give other information allowing the procurement procedure to be unequivocally identified (e.g. reference of a publication at national level):

INFORMATION ABOUT THE PROCUREMENT PROCEDURE

This information must be filled in by the Contracting Authority

Identity of the procurer ⁽²⁾	Answer
Name:	The Medical College of Wisconsin, Inc.
Which procurement is concerned?	Service
Title or short description of the procurement ⁽³⁾ :	In vivo study: Chinchilla model (tympanic membrane)
File reference number attributed by the contracting authority or contracting entity (if applicable) ⁽⁴⁾ :	N/A

All other information in all sections of the ESPD to be filled in by the economic operator

¹ For contracting authorities: either a prior Information Notice used as a means for calling competition or a Contract Notice

² Information to be copied from Section 1, point I.1, of the relevant notice. In case of joint procurement, please indicate the names of all involved procurers. ³

See points II.1.1 and II.1.3 of the relevant notice

⁴ See point II.1.1 of the relevant notice

Part II: Information concerning the economic operator

A: INFORMATION ABOUT THE ECONOMIC OPERATOR

Identification:	Answer
Name:	The Medical College of Wisconsin, Inc.
VAT-number, if applicable : If no VAT-number is applicable, please indicate another national identification number, if required and applicable	39-0806261
Postal Address:	8701 Watertown Plank Road, Milwaukee, WI 53226
Contact person or persons ⁽¹⁾ :	██████████
Telephone:	██████████
E-mail:	██████████
Internet address (web address) (if applicable)	
General Information:	Answer:
Is the economic operator a Micro, a Small or a Medium-Sized Enterprise ⁽²⁾ ?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Only in case the procurement is reserved ⁽³⁾: is the economic operator a sheltered workshop, a 'social business' ⁽⁴⁾ or will it provide for the performance of the contract in the context of sheltered employment programmes?	Yes <input type="checkbox"/> No <input type="checkbox"/>

¹ Please repeat the information concerning contact persons as many times as needed.

² Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium sized enterprises, (OJ L 124, 20.5.2003, p36)

This information is required for statistical purposes only

Micro enterprises: enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.

Small enterprises: an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR10 million

Medium enterprises: enterprises which are neither micro nor small and which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50million, and/or an annual balance sheet total not exceeding EUR 43 million.

³ See contract notice point III.1.5

⁴ i.e. its main aim is the social and professional integration of disabled or disadvantaged persons.

<p>If yes,</p> <p>What is the corresponding percentage of disabled or disadvantaged workers?</p> <p>If required, please specify which category or categories of disabled or disadvantaged workers the employees concerned belong to?</p>	<p>Click here and insert details</p>
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<p>If applicable, is the economic operator registered on an official list of approved economic operators or does it have an equivalent certificate (e.g. under a national (pre)qualification system)?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input checked="" type="checkbox"/></p>
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<p>If yes: Please answer the remaining parts of this Section, Section B and, where relevant, C of this part, complete Part V, where applicable, and, in any case, fill in and sign Part VI.</p>	
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<p>(a) Please provide the name of the list or certification and the relevant registration or certification number, if applicable:</p>	<p>Click here and insert details</p>
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<p>(b) If the certificate of registration or certification is available electronically, please state:</p>	<p>(web address, issuing authority or body, precise reference of the documentation)</p>
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<p>(c) Please state the references on which the registration or certification is based, and, where applicable, the classification obtained in the official list ⁽⁵⁾:</p>	<p>Click here and insert details</p>
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<p>(d) Does the registration or certification cover all of the required selection criteria?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
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⁵ The references and the classification, if any, are set out on the certification.

<p>If no:</p> <p>In addition, please complete the missing information in Part IV, Sections A, B, C or D as the case may be</p> <p>ONLY if this is required in the relevant notice or procurement documents;</p> <p>(e) Will the economic operator be able to provide a certificate with regard to the payment of social security contributions and taxes or provide information enabling the contacting authority or contracting entity to obtain it directly by accessing a national database in any Member State that is available free of charge?</p>	<p>Click here and insert details</p>
<p>If the relevant documentation is available electronically, please indicate:</p>	<p>(web address, issuing authority or body, precise reference of the documentation)</p>

Form of Participation:	Answer:
<p>Is the economic operator participating in the procurement procedure together with others ⁽⁶⁾?</p>	<p>Yes <input type="checkbox"/> No XXX</p>
<p>If yes, please ensure that the others concerned provide a separate ESPD form.</p>	
<p>If yes:</p> <p>(a) Please indicate the role of the economic operator in the group (leader, responsible for specific tasks.):</p>	<p>Click here and insert details</p>
<p>(b) Please identify the other economic operators participating in the procurement procedure together:</p>	<p>Click here and insert details</p>
<p>(c) Where applicable, name of the participating group:</p>	<p>Click here and insert details</p>
Lots:	Answer:
<p>Where applicable, indication of the lot(s) for which the economic operator wishes to tender:</p>	<p>Click here and insert details</p>

⁶ Notably as part of a group, consortium, joint venture or similar.

B: INFORMATION ABOUT REPRESENTATIVES OF THE ECONOMIC OPERATOR

Where applicable, please indicate the name(s) and address(es) of the person(s) empowered to represent the economic operator for the purposes of this procurement procedure:

Representation, if any:	Answer:
Full Name:	
Accompanied by the date and place of birth, if required	████████████████████
Position/Acting in the capacity of:	██
Postal Address:	██ ██
Telephone:	████████████████
E-mail:	██
If needed, please provide detailed information on the representation (its forms, extent, purpose...):	N/A

C: INFORMATION ABOUT RELIANCE ON THE CAPACITIES OF OTHER ENTITIES

Reliance:	Answer:
Does the economic operator rely on the capacities of other entities in order to meet the selection criteria for this Competition as set out in part 3.2 of the RFT and the criteria and rules (if any) set out under Part V below?	<p style="text-align: right;">No xxx</p> <p>Yes <input type="checkbox"/></p>

If yes, please provide a separate ESPD form setting out the information required under **Sections A and B of this Part and Part III for each** of the entities concerned, duly filled in and signed by the entities concerned.

Please note that this should also include any technicians or technical bodies, not belonging directly to the economic operator's undertaking, especially those responsible for quality control and, in the case of public works contracts, the technicians or technical bodies upon whom the economic operator can call in order to carry out the work.

Insofar as it is relevant for the specific capacity or capacities on which the economic operator relies, please include the information under Part IV for each of the entities concerned ⁽⁷⁾.

D. INFORMATION CONCERNING SUBCONTRACTORS ON WHOSE CAPACITY THE ECONOMIC OPERATOR DOES NOT RELY

Subcontracting:	Answer:
Does the economic operator intend to subcontract any share of the contract to third parties?	<p>Yes <input type="checkbox"/> No XXX</p> <p>If yes and in so far as known, please list the proposed subcontractors</p> <p>Click here and insert details</p>

Please provide the information required under Section A and B of this part [Delete if not applicable: and Part III] for each of the subcontractors concerned.

⁷ E.g. for technical bodies involved in quality control: Part IV, Section C, point 3.

Part III: Exclusion grounds

A: GROUNDS RELATING TO CRIMINAL CONVICTIONS

Article 57 (1) of Directive 2014/24/EU sets out the following reasons for exclusions:

1. Participation in a criminal organisation ⁽⁸⁾;
2. Corruption ⁽⁹⁾;
3. Fraud⁽¹⁰⁾;
4. Terrorist offences or offences linked to terrorist activities ⁽¹¹⁾;
5. Money laundering or terrorist financing ⁽¹²⁾;
6. Child labour and other forms of trafficking in human beings ⁽¹³¹⁴¹⁵⁾.

Grounds relating to criminal convictions under national provisions implementing the grounds set out in Article 57(1) of the Directive:	Answer:
Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction for one of the reasons listed above, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable?	Yes <input type="checkbox"/> No XXX
If yes , please indicate ⁽¹⁹⁾ :	If the relevant documentation is available electronically, please indicate: (web address, issuing authority or body, precise reference of the documentation) ⁽¹⁸⁾ :
(a) Date of conviction, specify which of points 1 to 6 is concerned and the reason(s) for the conviction,	date, point(s), reason(s)
(a) Identify who has been convicted:	Click here and insert details

⁸ As defined in Article 2 of Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime (OJ L 300, 11.11.2008, p. 42).

⁹ As defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, OJ C 195, 25.6.1997, p. 1, and in Article 2(1) of Council Framework Decision 2003/568/JHA of 22 July 2003 on combating corruption in the private sector (OJ L 192, 31.7.2003, p. 54). This exclusion ground also includes corruption as defined in the national law of the contracting authority (contracting entity) or the economic operator.

¹⁰ Within the meaning of Article 1 of the Convention of the protection of the European Communities' financial interests (OJ C 316, 27.11. 1995, p. 48).

¹¹ As defined in Articles 1 and 3 of Council Framework Decision of 13 June 2002 on combating terrorism (OJ L 164, 22.6.2002, p.3). this exclusion ground also includes inciting or aiding or abetting or attempting to commit an offence, as referred to in Article 3 of that Framework Decision.

¹² As defined in Article 1 of the Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing (OJ L 309, 25.11.2005, p. 15).

¹³ As defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims and replacing Council Framework Decision 2002/629/JHA (OJ L 101, 15. 4.2011 p. 1).

¹⁴ Please repeat as many times as needed.

¹⁵ Please repeat as many times as needed.

(b) Insofar as established directly in the conviction:	Click here and insert length of the period of exclusion and the point(s) concerned
	If the relevant documentation is available electronically, please indicate: (web address, issuing authority or body, precise reference of the documentation) ⁽¹⁶⁾ :
In case of convictions, has the economic operator taken measures to demonstrate its reliability despite the existence of a relevant ground for exclusion ⁽¹⁷⁾ ('Self Cleaning')	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes , please describe the measures taken ^(18,19)	Click here and insert details

B: GROUNDS RELATING TO THE PAYMENT OF TAXES OR SOCIAL SECURITY CONTRIBUTIONS

Payments of taxes or social security contributions:	Answer:	
Has the economic operator met all its obligations relating to the payment of taxes or social security contributions , both in the country in which it is established and in the Member State of the contracting authority if other than the country of establishment?	Yes	No <input type="checkbox"/>
If the relevant documentation concerning payment of taxes or social contributions is available electronically, please indicate:	Click here and insert details (web address, issuing authority or body, precise reference of the documentation) ⁽²³⁾ :	
If not , please indicate:	Taxes:	Social Contributions:
(a) Country or Member State concerned	Click here and insert details	Click here and insert details
(b) What is the amount concerned?	Click here and insert details	Click here and insert details
(c) How has this breach of obligations been established:	Click here and insert details	Click here and insert details

¹⁶ Please repeat as many times as needed.

¹⁷ In accordance with national provisions implementing Article 57(6) of Directive 2014/24/EU.

¹⁸ Taking into account the character of the crimes committed (punctual, repeated, systematic...) the explanation should show the adequacy of the measures to taken.

¹⁹ Please repeat as many times as needed

(1) Through a judicial or administrative decision		
<input type="checkbox"/> Is this decision final and binding?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<input type="checkbox"/> Please indicate the date of conviction or decision.		
<input type="checkbox"/> In case of a conviction, insofar as established directly therein , the length of the period of exclusion:	Click here and insert details	Click here and insert details
(2) By other means? Please specify:	If Yes, click here and insert details	If Yes, click here and insert details
(d) Has the economic operator fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
If the relevant documentation concerning payment of taxes or social contributions is available electronically, please indicate:	Click here and insert details (web address, issuing authority or body, precise reference of the documentation) ⁽²⁰⁾ :	

C: GROUNDS RELATING TO INSOLVENCY, CONFLICTS OF INTEREST OR PROFESSIONAL MISCONDUCT

(²¹

²²

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Please note that, for the purpose of this procurement, some of the following exclusion grounds may have been defined more precisely, in national law, in the relevant notice or the procurement documents. Thus, national law may for instance provide that the notion of 'grave professional misconduct' may cover several different forms of conduct.

Information concerning possible insolvency, conflict of interest or professional misconduct	Answer:
	Yes <input type="checkbox"/> No XXX

²⁰ Please repeat as many times as needed

²¹ See Article 57(4) of Directive 2014/24/EU

²² As referred to for the purposes of this procurement in national law, in the relevant notice or the procurement documents or in Article 18(2) of Directive 2014/24/EU.

<p>Has the economic operator, to its knowledge, breached its obligations in the fields of environmental, social and labour law ⁽²⁶⁾?</p>	<p>If yes, has the economic operator taken measures to demonstrate its reliability despite the existence of these grounds for exclusion ('Self Cleaning')?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If it has, please describe the measures taken: Click here and insert details</p>
	<p>Is the economic operator in any of the following situations:</p>

<p>(a) Bankrupt, or</p> <p>(b) The subject of insolvency or winding-up proceedings, or</p> <p>(c) In an arrangement with creditors, or</p> <p>(d) In any analogous situation arising from a similar procedure under national laws and regulations ⁽²³⁾, or</p> <p>(e) That its assets are being administered by a liquidator or by the court, or</p> <p>(f) That its business activities are suspended?</p>	<p>Yes <input type="checkbox"/> No XXX</p>
<p>If yes: Please provide details:</p>	<p>Click here and insert details</p>
<p>Please provide the reasons for being able nevertheless to perform the contract, taking into account the applicable national rules and measures on the continuation of business in those circumstances ⁽²⁴⁾</p>	<p>Click here and insert details</p>
<p>If the relevant documentation is available electronically, please indicate:</p>	<p>Click here and insert details (web address, issuing authority or body, precise reference of the documentation):</p>
	<p>Yes <input type="checkbox"/> No XXX</p>
	<p>Click here and insert details</p>

²³ See national law, the relevant notice or the procurement documents

²⁴ This information need not be given if exclusion of economic operators in one of the cases listed under letter a to f has been made mandatory under the applicable national law without any possibility of derogation where the economic operator is nevertheless able to perform the contract.

<p>Is the economic operator guilty of grave professional misconduct ⁽²⁵⁾?</p> <p>If yes, please provide details</p>	<p>If yes has the economic operator taken selfcleaning measures?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
	<p>If it has, please describe the measures taken: Click here and insert details</p>
<p>Has the economic operator entered into agreements with other economic operators aimed at distorting competition?</p> <p>If yes, please provide details:</p>	<p>Yes <input type="checkbox"/> No XXX</p>
	<p>Click here and insert details</p>
	<p>If yes has the economic operator taken selfcleaning measures?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>

	<p>If it has, please describe the measures taken: Click here and insert details</p>
<p>Is the economic operator aware of any conflict of interest ⁽²⁶⁾ due to its participation in the procurement procedure?</p> <p>If yes, please provide details</p>	<p>Yes <input type="checkbox"/> No XXX</p>
	<p>Click here and insert details</p>
<p>Has the economic operator or an undertaking related to it advised the contracting authority or contracting entity or otherwise been involved in the preparation of the procurement procedure?</p> <p>If yes, please provide details</p>	<p>Yes <input type="checkbox"/> No XXX</p>
	<p>Click here and insert details</p>

²⁵ Where applicable, see definitions in national law, the relevant notice or the procurement documents.

²⁶ As indicated in national law, the relevant notice or the procurement documents.

<p>Has the economic operator experienced that a prior public contract or a prior concession contract was terminated early, or that damages or other comparable sanctions were imposed in connection with that prior contract?</p> <p>If yes, please provide details:</p>	<p>Yes <input type="checkbox"/> No XXX</p>
	<p>Click here and insert details</p>
	<p>If yes has the economic operator taken selfcleaning measures?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
	<p>If it has, please describe the measures taken:</p> <p>Click here and insert details</p>
<p>Can the economic operator confirm that:</p> <p>(a) It has not been guilty of serious misinterpretation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment if the selection criteria,</p> <p>(b) It has not withheld such information,</p> <p>(c) It has been able, without delay, to submit the supporting documents required by a</p>	<p>Yes XXX No <input type="checkbox"/></p>
<p>contracting authority or contracting entity, and</p> <p>(d) It has not undertaken to unduly influence the decision making process of the contracting authority or contracting entity, to obtain confidential information that may confer upon it undue advantages in the procurements procedure or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award?</p>	

Part IV: Selection Criteria

Concerning the selection criteria (Section α of this part), the economic operator declares that:

α : GLOBAL INDICATION FOR ALL SELECTION CRITERIA

Meeting all required selection criteria	Answer
It satisfies the required selection criteria for this Competition as set out in part 3.2 of the RFT:	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Part V: Reduction of the number of qualified candidates

Not applicable

Part VI: Concluding statements

The undersigned formally declare that the information stated under Parts II – III above is accurate and that it has been set out in full awareness of the consequences of serious misrepresentation.

The undersigned formally declare to be able, upon request and without delay, to provide the certificates and other forms of documentary evidence referred to, except where:

- (a) The contracting authority has the possibility of obtaining the supporting documentation concerned directly by accessing a national database in any Member State that is available free of charge^(27), or*
- (b) As of 16 February 2021 at the latest (²⁸), the contracting authority or contracting entity already possesses the documentation concerned.*

The undersigned formally consent to The Royal College of Surgeons in Ireland gaining access to documents supporting the information, which has been provided in this European Single Procurement Document for the purposes of tender request - In vivo study: Chinchilla model (tympanic membrane

Date, place and signature(s):

Signed: (Authorised Signatory)	
Block Capitals:	████████████████████
Position:	██
Company:	THE MEDICAL COLLEGE OF WISCONSIN, INC.
Registered Office:	8701 WATERTOWN PLANK ROAD
	MILWAUKEE, WISCONSIN, USA, 53226
Date:	2/18/2021

²⁷ On condition that the economic operator has provided the necessary information (web address, issuing authority or body, precise reference of the documentation) allowing the contracting authority or contracting entity to do so. Where required, this must be accompanied by the relevant consent to such access.

²⁸ Depending on the national implementation of the second subparagraph of Article 59(5) of Directive 2014/24/EU