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Public Contracts Review Board
Department of Contracts
Notre Dame Ravelin
Floriana VLT2000

23 February 2024

Dear Sirs,

Re: Tender for the Supply of 3.5ml Serum tubes with serum separator and clot activator with Reference Number CfT020-3452/23 – CPSU5700/2023 (the "Tender")

1. We have been instructed by **OK Medical LTD (C 79739)** (the "**Appellant**") to file an appeal in terms of Article 270 of the Public Procurement Regulations (the "**PPR**") in connection with the above-captioned Tender.

2. On 11 April 2023, the Central Procurement and Supplies Unit (the "**Contracting Authority**") published the above-captioned Tender for the supply of 3.5ml serum tubes with serum separator and clot activator. The estimated procurement value for this call for Tenders was €91,757 (excluding VAT) for an estimated quantity of 1,296,000 units. The Tender was to be awarded in accordance with the sole criterion of price in accordance with Clause 6.

3. The Appellant received a letter of rejection from the Contracting Authority on 16 February 2024 (as per the letter of rejection attached and marked as "**Document OM1**") whereby it was informed that its bid was being rejected on the basis of technical non-compliance:

> *The Declaration of conformity (DOC) is invalid since the product code or product identifier for the offered product is not listed.*

4. As shall be explained hereunder, the Appellant is aggrieved by the Contracting Authority's decision.

Ground of Appeal: the Appellant's EU Declaration of Conformity (D.O.C.) is compliant with the pertinent EU legislation, namely Regulation 2017/746 on In Vitro Diagnostic Medical Devices.

5. For this Board's benefit, "in vitro" is a Latin term that translates to "in glass". The product in procurement is serum tubes which classify as in vitro medical devices regulated by Regulation 2017/746 on In Vitro Diagnostic Medical Devices (the "**IV Regulation**"). The IV Regulation is directly applicable in Malta and local binds economic operators.

6. In vitro devices must be accompanied by a declaration of conformity in accordance with Clause 2.3(ii) of Section 3 – Specifications on page 23 of the Tender document which requires:

A valid Declaration of Conformity for product being offered and references to the relevant harmonised standards used (applicable if product falls under the Medical Devices Regulation [MDR; Regulation (EU) 2017/745], In vitro Medical Diagnostic Devices Regulation [IVDR]).

7. The Appellant's D.O.C. (attached and marked as "**Document OM2**"), which was submitted as part of its technical literature, is fully compliant with the IV Regulation. Article 17 of this Regulation cross-refers to the details laid out in its Annex IV which details must be present in the D.O.C. For ease of reference, Article 17 and Annex IV are being reproduced as an extract in an appendix to this appeal (attached and marked as "**Document OM3**").

8. For the avoidance of doubt, the Appellant's Technical Offer including the supporting technical literature submitted by the Appellant with its bid (other than that which is publicly available) is strictly confidential and is not to be disclosed to any party or entity other than this Honourable Board.

9. For the purpose of this appeal, the relevant parts of Annex IV are Point 3 and Point 4:

3. The Basic UDI-DI as referred to in Part C of Annex VI;

*4. Product and trade name, **product code*** (emphasis added), *catalogue number **or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity*** (emphasis added), *such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3.*

10. As defined in Article 24 of the IV Regulation, "Basic UDI-DI" stands for Unique Identification System device identifier. The Basic UDI-DI serves as the "*primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity*" (see Part C of Annex VI).

11. The Appellant's D.O.C. contains this Basic UDI-DI:

Basic UDI-DI: 697547397030010001YC

12. Now Point 4 of Annex IV expressly allows for the product code to be provided by the Basic UDI-DI(!):

Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3.

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13. With respect, the Appellant submits that it is baffling how its offer can be disqualified because its EU D.O.C. does not include the product code when the IV Regulation itself states, black on white, that the product code can be integral to the Basic UDI-DI.

14. In so doing, the Contracting Authority has failed to comply with the general principles of public procurement *inter alia* self-limitation and proportionality.

15. In view of the above, the Appellant contends that its offer was the cheapest technically compliant offer tendered and consequently the Contracting Authority's decision to disqualify it was unlawful.

THEREFORE, in view of the above and for other reasons that may be brought in due course at law, the Appellant humbly requests that this Public Contracts Review Board:

a. declares that the Contracting Authority's decision of 16 February 2024 is wrong and/or unlawful;

b. consequently, quashes the Contracting Authority's decision of 16 February 2024;

c. orders the refund of the deposit paid to the Appellant;

subject to any declaration or order as it deems fit and opportune.

Yours sincerely,

Ganado Advocates

Dr. Clement Mifsud Bonnici
(cmifsudb@ganado.com)

Dr. Calvin Calleja
(ccalleja@ganado.com)

Dr. Krista Refalo
(krefalo@ganado.com)

DOCUMENT OM1

CENTRAL PROCUREMENT & SUPPLIES UNIT
MINISTRY FOR HEALTH
c/o SUB002 San Gwann Industrial Estate, San Gwann. SGN3000
Tel: (+356) 2540 4000 E-mail: info.cpsu@gov.mt

CFT Reference: 020-3452/23 CPSU5700/23

Date: 16th February, 2024

Messrs OK Medical Ltd

Tender for the supply of 3.5ml Serum tubes with serum separator and clot activator.

Reference is made to your offer made in respect to the abovementioned tender.

The Departmental Contracts Committee (DCC) - Ministry for Health has accepted the recommendation of the Evaluation Committee, to reject the offer submitted by your organisation for the tender in caption.

Reason for Rejection: Offer: 192049 The Declaration of conformity (DOC) is invalid since the product code or product identifier for the offered product is not listed. DOC is Note 3 and non rectifiable.

Offer TID: 192050 A cheaper technically compliant offer was recommended.

For your information the Evaluation Committee recommended that the contract should be awarded to Drugsales Ltd at pack of 100 tubes at €6.39.

If you intend to object to this decision, the Public Procurement Regulations allow for an official objection which in this case has to be lodged electronically with the Public Contracts Review Board by sending an email on: info.pcrb@gov.mt by noon of 26th February, 2024 against a deposit of €400.

Payments are to be made through bank transfer in terms of the following details:

Name of Account Holder	Cashier Malta Government
Name of Bank	Central Bank of Malta
Address of Bank	Castille Place, Valletta
Account Number	40001EUR-CMG5-001-H
BIC	MALT MT MT
IBAN Code	MT55MALT011000040001EURCMG5001H
Bank Code	01100

The official schedule can be accessed on the website: www.etenders.gov.mt.

Although we have not been able to make use of your services on this occasion, I trust that you will continue to take an active interest in our initiatives.

Yours sincerely

Marika Cutajar

Chairperson
Evaluation Committee

DOCUMENT OM2

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Changsha Renji Medical Equipment Co., Ltd. 201, Stage 4, Changsha E Center, No.18 Xiangtai Road, Liuyang Jingkai District, Changsha City, 410300,Hunan Province, China
SRN:	CN-MF-000030318
European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
SRN:	ES-AR-000019366
Product Name:	Blood Collection Tube
Product Model:	100 tests/kit
Intended Use:	Blood Collection Tube is used to collect, transport, store and process blood for testing serum, plasma or whole blood in the clinical laboratory and are for professional use.To be used in conjunction with a disposable blood collection needle. Blood Collection Tube and Needles are used together as a system for the collection of venous blood.
EMDN:	W0501010102
Basic UDI-DI:	697547397030010001YC
Classification acc. to IVDR Ax. VIII:	Class A , Rule 5 (b) of IVDR Annex Ⅷ
Conformity Assessment Procedure:	Article 48 (10), IVDR (EU) 2017/746

STANDARDS APPLIED:

EN ISO 14971:2019	EN ISO 18113-1:2013	EN 13612:2002
EN ISO 13485:2016	EN ISO 18113-2:2013	EN 62366:2015
EN ISO 23640:2016	EN ISO 15223-1:2016	EN 13641:2015
ISO/TR 24971:2020	ISO 20916:2019	EN 14820:2004

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

China
Oct 1, 2022
Place, date

Renjiang Li
CEO
Renjiang Li
Legally binding signature, Function

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with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.

Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, *inter alia*, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities referred to in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

Article 17

EU declaration of conformity

1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device. The declaration shall contain all the information required for identification of the Union legislation to which the declaration relates.

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3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission is empowered to adopt delegated acts in accordance with Article 108 amending the minimum content of the EU declaration of conformity set out in Annex IV in the light of technical progress.

Article 18

CE marking of conformity

1. Devices, other than devices for performance studies, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex V.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 48. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

6. Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

Article 19

Devices for special purposes

1. Member States shall not create obstacles to devices for performance study being supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 57 to 76, and in the implementing acts adopted pursuant to Article 77.

2. The devices referred to in paragraph 1 shall not bear the CE marking, with the exception of the devices referred to in Article 70.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create obstacles to the showing of devices which do not comply with this Regulation, provided that a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with this Regulation.

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ANNEX IV

EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain the following information:

1. Name, registered trade name or registered trade mark and, if already issued, SRN referred to in Article 28 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;

2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;

3. The Basic UDI-DI as referred to in Part C of Annex VI;

4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;

5. Risk class of the device in accordance with the rules set out in Annex VIII;

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;

7. References to any CS used and in relation to which conformity is declared;

8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;

9. Where applicable, additional information;

10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

APS BANK Plc

Registration Number: C 2192
Address: APS Centre, Tower Street B'Kara BKR 4012

Transaction Reference: 212788490
Printed On: 11:2023.02.2024
Printed By: GLENN LUCAS

Transfer to a non-APS account

From Account: **40715610011**

Status: **Authorized**

Currency: **EUR**

Amount:	400.00
To Account:	MT55MALT011000040001EURCMG5001H
Payment Date:	23.02.2024
Payment Reference:	CPSU5700/23 OK MEDICAL
Fee:	0
Charges:	SHA
Sort Code:	
Swift Code:	MALTMTMTXXX
Beneficiary Bank Name:	CENTRAL BANK OF MALTA
Beneficiary Bank Address Line 1:	CASTILLE PLACE
Beneficiary Bank Address Line 2:	VALLETTA
Beneficiary Bank Country:	MALTA
Beneficiary Name:	CASHIER MALTA GOVERNMENT
Beneficiary Address Line 1:	MALTA
Beneficiary Address Line 2:	
Beneficiary ZIP Code:	
Beneficiary City:	MALTA
Beneficiary Country:	MALTA

Intermediary Bank Swift Code: