PUBLIC CONTRACTS REVIEW BOARD

Case 1840 – CFT 009-0596/22 (CPSU 422/22) – Supplies Tender – Tender for the Provision of MRI Proof Anaesthetic Machine with Reduced Environmental Impact

6th February 2023

The Board,

Having noted the letter of objection filed by Dr Alessandro Lia acting for and on behalf of Prohealth Limited, (hereinafter referred to as the appellant) filed on the 14th November 2022;

Having also noted the letter of reply filed by Dr Leon Camilleri acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 22nd November 2022;

Having heard and evaluated the testimony of the witness Ms Celia Falzon (Representative of Mater Dei Hospital) as summoned by Dr Alessandro Lia acting for Prohealth Limited;

Having heard and evaluated the testimony of the witness Mr Jimmy Bartolo (Member of the Evaluation Committee) as summoned by Dr Alessandro Lia acting for Prohealth Limited;

Having heard and evaluated the testimony of the witness Engineer Chris Attard Montalto (Representative of Mater Dei Hospital) as summoned by Dr Alessandro Lia acting for Prohealth Limited;

Having heard and evaluated the testimony of the witness Mr Stephen Sciberras (Member of the Evaluation Committee) as summoned by Dr Alessandro Lia acting for Prohealth Limited;

Having heard and evaluated the testimony of the witness Mr Claude Portanier Mifsud (Representative of Mater Dei Hospital) as summoned by Dr Alessandro Lia acting for Prohealth Limited;

Having taken cognisance and evaluated all the acts and documentation filed, as well as the submissions made by representatives of the parties;

Having noted and evaluated the minutes of the Board sittings of the 19th January 2023 and 2nd February 2023 hereunder-reproduced.

Minutes

Case 1840 – CfT 009-0596/22 – Supplies Tender – Tender for the Provision of MRI Proof Anaesthetic Machine with reduced Environmental Impact.

The tender was issued on the 24th May 2022 and the closing date was the 14th June 2022. The estimated value of the tender excluding VAT, was € 84,745.70.

On the 14th November 2022 Prohealth Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that their offer was deemed not to be technically compliant.

A deposit of € 423.73 was paid.

There were three (3) bids.

On the 19th January 2023 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Ms Stephanie Scicluna Laiviera and Dr Vincent Micallef as members convened a public virtual hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Prohealth Ltd

Dr Alessandro Lia	Legal Representative
Mr Mark Bondin	Representative

Contracting Authority – Central procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Karen Scicluna	Chairperson Evaluation Committee
Mr Albert Incorvaja	Secretary Evaluation Committee
Mr Stephen Sciberras	Evaluator
Mr Jimmy Bartolo	Evaluator

Preferred Bidder – Ovil Group of Companies

Ms Sandy Breen	Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Alessandro Lia Legal Representative for Prohealth Ltd requested witnesses be heard first.

Ms Celia Falzon (473265M) called as a witness by Appellant when requested to refer to the policies on the use of MRI equipment at Mater Dei Hospital (MDH) stated that she had not been notified that this was required of her.

The Chairman pointed out that an e-mail from the Board had specifically requested the applicable policies and protocols at MDH to be produced. The Board agreed to defer hearing the testimony of this witness to enable the necessary documents to be made available.

Mr Jimmy Bartolo (228464M) called as a witness by Appellant testified on oath that he is the Biomedical Operations Manager at MDH and that this was a technical rather than a medical role. He was also one of the evaluators. He stated that the Tender Evaluation Committee (TEC) requested a clarification and from the reply it was established that the gaussmeter alarm is not available during use of the machine. The indication is that the alarm operates only when the power supply is on. There are several references in the operating manual indicating the fact that the gaussmeter has to be switched off. The main use of the machine is to overcome the problem of a patient moving and the point of the gauss is to determine how near the machine can be placed to the near magnet of the MRI equipment.

Witness explained that during treatment the machine has to be moved occasionally during treatment to accommodate extra nurses and or doctors as required in the theatre. Through switching off, the machine reduces safety. The machine offered by Appellant does not give an alarm if placed near a magnet thus creating a danger to the personnel using it. Referred to the technical specifications of the tender, sections 6.3.1 and 7.0 to 7.2 witness stated that the training element is considered by the TEC as a general condition. Unless precautions are taken there could be devastating results if there is no alarm and the machine is attracted by the magnet.

Questioned by Dr Camilleri witness said that the machine is used in the MRI procedures when sometimes there are serious health situations. The MRI magnet is extremely powerful and operates on several frequencies and if that magnet attracts the machine it could lead to disaster and even death of a patient. If the machine is moved very near the magnet an alarm alerts personnel. A machine where a gaussmeter is switched off, as in this case, is useless as it provides no protection. The user manual [pages indicated] clearly states that the machine has to be switched off before operations begin. Witness confirmed that there are instances where extra personnel have to intervene in procedures and that in the case of the machine offered by Appellant there is nothing to indicate that the machine is being moved closer to the MRI.

Further questioned by Dr Lia, witness said that he does not believe that the tender stated the need for an on/off switch as this is accepted that it is part of the safety procedures. The tape is put down to make sure that distances are respected but the machine does sometimes have to be moved in cases of emergency whilst clinical treatment is being given. Witness agreed that the machine is provided with brakes which can be locked. When the MRI is not in use the machine is removed from the room by trained personnel.

Engineer Chris Attard Montalto (260567M) called to testify by the Appellant stated on oath when asked what he understood by the term 'machine should be able to protect itself…..' that the machine protects itself by alarming the user. He explained the different distances required for different gaussmeters and that the higher the gauss the nearer the machine can be moved to the magnet.

Questioned by Dr Camilleri, witness said that he was responsible for all machinery at the Ministry for Health and that the magnetic field is extremely high in a MRI environment. There is serious danger of the machine being attracted by the magnet with the ensuing result of harm to a patient and great expense to put right the equipment.

Mr Stephen Sciberras (593778M) called to testify by the Appellant stated on oath that he is an Anaesthetist by profession and knows the make of the machine in question very well. He explained that during MRI some movement is likely in circumstances when the patient is anaesthetised and this created the possibility that the machine is moved nearer the MRI. The Health & Safety Officer sticks tape on the floor to indicate the limit on 1000 gauss -this would be about half-a-metre distance from the patient. Witness said that he regularly uses the MRI room and is familiar with the arrangements although others, apart from the anaesthetists, use it. There is no difference to the user how near it is placed, although 1000 gauss is the limit, so long as there are safety measures. Witness is aware of instances where the machine was moved.

According to the witness, the tender required bidder to state what the safety features were and how they operate had to be stated in the bid. One cannot have a situation where distances had to be recalculated every time there is some movement and the clause in the tender was meant to cover the mechanism for these various levels of safety. If you have a situation of a patient in an extreme health situation the operator does not have the chance to check distances visually and hence the need for an

alarm. Although the MRI is used by specialists, said the witness, in an emergency they might not be aware of the set-up in a full room. Trainees are usually accompanied by a trained supervisor who is fully aware what the alarm signifies.

Questioned by Dr Camilleri, witness said that the chosen machine had light bulbs alarms which were triggered as the magnetic field grew, which objectors machine did not have as it is switched off. The need to switch off is confirmed according to the machine manual. The size of the machine is not small and it is heavy and rather hefty as it is made of a special metal. The magnetic field is exponential. If the machine is attracted by the magnet it could have serious consequences on the patient and several week idleness of the equipment.

At this stage Dr Camilleri notified the Board that he had been advised that the Hospital MRI policies are an internal matter and are not made public as they are solely for the use of the practitioners.

Dr Lia objected to this and said that these are matters that should be known by the public.

After further discussion the Chairman said that the Board needed a short recess to consider the points raised.

On resumption the Chairman stated that the Board, following the request by Dr Lia directs that any question relating to the mentioned policies and protocols should be specifically indicated to the PCRB for them to communicate such questions, or selected questions, to the CPSU. Consequently the Board directs the CPSU to reply to these questions and provide extracts forming the basis of these replies which will be strictly expedited to the PCRB.

The Chairman thanked the parties for their submissions and deferred the hearing to the 2nd February 2023 at 9.00am.

End of Minutes.

SECOND HEARING

On the 2nd February 2023 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Ms Stephanie Scicluna Laiviera and Dr Vincent Micallef as members convened a public virtual hearing to further consider this appeal.

The attendance for this public hearing was as follows:

Appellant – Prohealth Ltd

Dr Alessandro Lia	Legal Representative
Mr Mark Bondin	Representative

Contracting Authority – Central procurement and Supplies Unit

Dr Leon Camilleri	Legal Representative
Ms Karen Scicluna	Chairperson Evaluation Committee
Mr Albert Incorvaja	Secretary Evaluation Committee
Mr Stephen Sciberras	Evaluator
Mr Jimmy Bartolo	Evaluator
Eng Chris Attard Montalto	Representative

The Chairman welcomed the parties and noted that at the last hearing it was agreed that the PCRB would deal with questions raised on the policies and protocols dealing with the MRI at MDH, and that a witness will be heard in this regard.

Mr Claude Portanier Mifsud (127775M) testified on oath that access to the MRI Room is through an identification tag or authorised by a radiographer. The Control Room leading to the MRI Room is where other staff are usually located but with restricted access. The policy is that anyone entering the MRI Room is screened on entering but once in there no restrictions are in force. Access to the Control Room is controlled by the radiographer but there are no rules as to who is allowed access. There are usually more than one radiographer in this room which could also include doctors, nurses and other medical practitioners. Occasionally there might be security and fire prevention personnel. In the MRI Room everyone is aware that access is limited and that precautions are necessary due to the magnetic field. An identity tag is necessary to go into this Room.

In reply to questions from Dr Camilleri witness stated that apart from the radiographer they may be others that need to go into the MRI Room in case of emergencies – these could include parents of patients, anaesthetists and even cleaners if necessary, but only with the permission of the radiographer.

This concluded the testimony.

Dr Lia stated that the Contracting Authority disqualified Appellant on the basis that the machine offered safety risks to non-familiar users if the machine was moved too near the magnet. It has now been established that the machine offered by Prohealth has an alarm with instructions to switch it off whilst the MRI is in use. At MDH there is an indication line at 1000 gauss whilst the machine on offer is only 400 gauss and is therefore not suitable. The tender specifies that the machine 'must protect itself' – machines like that do not exist and do not apply to any bidder, according to Dr Lia. Having an alarm on a machine does not provide self-protection and the whole case is based on hypothesis and some unauthorised entry into the MRI Room. It is impossible for any person to have access to this Room and there is presumption of some absurd situation whether there is an alarm or not. Regulations are in force ensuring that the MRI Room is monitored at all times regarding entry and even in the case of a fire there are restrictions.

According to the testimony of Mr Bartolo, special training is given on the use of the machine, even on switching it off – anyone in that Room has special end-user training as required in the tender. It is an absurdity and an impossibility to think of an unauthorised person entering the MRI Room and moving the machine. No machine protects itself – the protection is in the line on the floor, the alarm and the brakes on the machine.

Dr Camilleri stated that he does not agree with the argument regarding unauthorised entry into the MRI Room. There is evidence that situations could include emergencies. Emergencies and negligence are two completely different matters. The MRI has massive magnetic force and hence the machine in question must be safe and able to protect itself. The tender is not based on the BPQR principle and therefor 1000 or 400 gauss make no difference as long as the parameters in the tender are met. Training or floor markers are not sufficient to meet an emergency and the technical conformity of the machine must be inbuilt. The requirement of the machine to protect itself does not mean the machine switching off. How can a machine protect itself if the manufacturer recommends switching it off during MRI use?

According to witness Mr Portanier, said Dr Camilleri, the possibility exists of an anxious parent going into the MRI Room; in that situation and the machine being moved only the sound will alarm the

radiographer that something is amiss. Tape markings on the floor are not much of a safety precaution in an emergency. In the circumstances, which machine to select, was an elementary decision on the members of the TEC – the machine that switches off or otherwise? Patients and workers have to be safeguarded and should not be exposed to risks. This was a clear criterion in the tender which was not challenged prior to tendering. The TEC was correct in their decision as they were dealing with a realistic situation in a sensitive area. Their decision should be confirmed.

Dr Lia in a concluding remark said that this situation has been stretched to making a case where the machine is not in use.

The Chairman thanked the parties for their submissions and declared the hearing closed.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sittings of the 19th January 2023 and 2nd February 2023.

Having noted the objection filed by Prohealth Limited (hereinafter referred to as the Appellant) on 14th November 2022, refers to the claims made by the same Appellant with regard to the tender of reference CFT 009-0596/22 (CPSU422/22) listed as case No. 1840 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Alessandro Lia
Appearing for the Contracting Authority:	Dr Leon Camilleri & Dr Alexia J Farrugia Zrinzo

Whereby, the Appellant contends that:

a) The reason for rejection given by CPSU is absolutely unfounded. The reason given by CPSU speaks of "non-familiar users" which might move the machine beyond the safe limit and bring it too close to the magnet and cause an accident. First and foremost, this reason is completely hypothetical and impossible, because it assumes that during the use of an MRI machine a non-familiar user enters the MRI room, and moves the machine whilst a patient is sedated and undergoing an MRI procedure. This reason is unfounded, not to say absurd.

b) Secondly, it is being assumed (and only by way of assumption) that a non-familiar user moves the machine during the MRI procedure. It is only obvious (especially for whoever has at some point in time underwent an MRI procedure) that no one at all enters the MRI room whilst an MRI

procedure is ongoing. In the extremely unlikely event that anybody enters the MRI room during an MRI procedure (due to any emergency to the patient), anybody entering the room would either be the MRI technician (clearly a person familiar with the machines) or a medical professional, who would have to attend to the patient and not move any machinery.

c) Furthermore, all such machines 'protect themselves' through an alarm by a gaussmeter. The requirement that the gaussmeter is on during the procedure is not mentioned in the tender document. In any case, the self-protection of the machine does not result through the gaussmeter. The gaussmeter measures the proximity to the magnetic field of the MRI machine and only alarms if brought too close. The gaussmeter on Prohealth's machine can be switched off during use only because no one should enter the MRI room during use. This can be bypassed and the gaussmeter can be left on. The notice is there only to save battery life. The gaussmeter's use is applicable only until positioning before use and thus during use any movement of the machine being the subject of this tender is absolutely unnecessary.

d) Moreover, by way of an additional clarification, Prohealth remarks that the same tender specifies that the bidder should specify modes of energy efficient optimisation stating the following: *"6.3 Training for Energy Efficiency Optimisation 6.3.1 The tenderer shall provide training that includes elements regarding adjustment and fine-tuning of the equipment's electricity using parameters (for example, standby mode) in order to optimise the electricity use. The training can be included in the clinical and technical education to be provided by the tenderer."* The notice that the machine is to be switched off during use is actually Prohealth's compliance with this section - and therefore cannot be penalised stating that it is technically non-compliant with another section of the tender.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 22nd November 2022 and its verbal submission during the virtual hearings held on 19th January 2023 and 2nd February 2023, in that:

a) The appellant argues that the reason provided by the evaluation committee is hypothetical and impossible. The expert members of the evaluation committee disagree for the following reasons. The MRI machine being procured as will be further explained by the evaluation committee, will not only be used by anaesthetists who specialise and carry out daily MRI procedures, but will also be used by practitioners in the Department of Anaesthesia who seldomly use an MRI anaesthetic machine, but will have to use it occasionally during urgent cases, even at night. For this reason, the machine has to be as user friendly, self-protective and patient protective as possible.

b) Moreover, it is very common that an anaesthetist enters into the MRI room during a procedure involving a general anaesthetic, to attend patients or move them, even in difficult situations. During such difficult and emergency situations, although ideally the equipment does not move, a situation where some equipment is moved for some reason or another is not unforeseeable and in fact

incidents in similar situations did occur in the past. The objector states that the requirement that the gaussmeter (magnetic field strength monitor) is kept on during the procedure is not mentioned in the tender document. The tender document requires a magnetic field strength monitor and requires also that "The machine should be able to protect itself from permanent damage if it brought too close to the magnet." The condition above quoted and emphasised in bold is clear, unambiguous and categorical - It does not state that such protection shall be available during the MRI procedure, it neither states that such protection shall be available before or after the MRI procedure - the statement is categorical, does not distinguish and therefore applied across the board at any time.

c) Contrary to the other products being offered in this tender, from the literature submitted it results that the machine does not switch off automatically when brought too close to the magnet. The only self protection of the objector's machine is therefore the alarm of gauss meter which indicates if the machine is moved too close to the magnet in a way that the situation becomes dangerous.

d) This has been confirmed by the objector after a request for rectification made by the evaluation committee. The evaluation committee requested the below: *"The Technical Literature provided does not corroborate the Technical Offer: Referring to Technical Specification 2.8.7; As the anesthetic (sic) machine and ALL its components shall be required to be MRI proof, and shall be used in an MRI environment, the unit shall be required to incorporate a magnetic field strength monitor. The machine should be able to protect itself from permanent damage if it brought too close to the magnet . Technical Literature provided does not show how this will be done. Submit detailed Technical Literature for the Field Strength Monitor showing clearly how it will measure magnetic strength and how the machine will protect itself if it is too close to the MRI magnet showing if it would still work, or would it shut down."* The objector reverted with the below reply: *"The Penlon Prima 451 anaesthesia machine offered by Prohealth in the above-mentioned tender call is safe for use in any MRI environment and can be positioned*

adjacent to the MRI scanner up to the 1000 gauss line as stated on page 29 of document 4 submitted with the offer (doc 4 is the user manual for Prima 451). The Gauss Meter mentioned on this page will obviously be provided with every machine purchased as this is part of the standard package for Penion Prima 451. Details of this Gauss Meter can be found on Page 38 of the same document referred to above. Gauss limit will be set upon installation. The gauss meter provided will alarm if the set gauss line is passed. In this way, the machine will be protected up to 1000 Gauss, which is practically a few centimetres away from the scanner:" It is therefore crystal clear that the Gauss meter is the only self protection that the machine offered has. This Gauss meter according to the literature of the product offered by the objector SHALL be switched off during the MRI procedure, thus leaving the anaesthetic machine with no protection/safety whatsoever and therefore in blatant breach of condition 2.8.7 quoted in the rejection letter.

e) The argument that the Gauss meter could remain on during the procedure, is at this stage inadmissible as the technical literature did not present the switching off of the Gauss meter as an option but as an important mandatory requirement. Page 29 of the user manual: *"CAUTION Switch*

the gauss meter OFF before any clinical procedures are started in the MR facility." Page 4 of the user manual: *"14. Switch the gauss meter OFF before any clinical procedures are started in the MR facility."* Page 38 of the user manual: *"Switch the gauss meter OFF before any clinical procedures are started in the MR facility."* The argument that the switching off, of the Gauss meter is for the purpose of satisfying the energy efficiency conditions, is an argument formulated post rejection with the aim of justifying the objector's machine shortage.

f) Moreover, in reply to the objector's remark on servicing, CPSU submits that such an obligation would be a contractual obligation of the contractor once a contract is signed and is not a matter to be syndicated at this stage once a bidder is committing itself of honouring the tender requirements, and there is no breach of the tender conditions and requirements.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will now consider Appellant's grievances.

a) Through the testimony under oath of various witnesses, it has been ascertained that on occasion, and whenever deemed necessary, entrance to the MRI room is granted to non-professional medical people. (specific reference to Mr Claude Portanier Mifsud testimony). Even though these non-professional medical people will have been screened by the on-duty radiographer and notified of best practices for health and safety measures, this Board opines that it cannot be assumed that they will be fully aware of procedures in relation to training which are mentioned in the tender dossier (reference to page 24 of the tender dossier, sections 6.3.1, 7.0, 7.1 and 7.2).

b) This Board opines that the Evaluation Committee was composed of knowledgeable technical people for it to properly assess the administrative and technical criteria relative to the subject matter of this tender procedure. They also followed well established public procurement praxis in that they went back to the economic operator, now Appellant, to request a clarification about the issue encountered.

c) The tender document was clear and unambiguous when it states *"As the anaesthetic machine and ALL its components shall be required to be MRI proof, and shall be used in an MRI environment, the unit shall be require to incorporate a magnetic field strength monitor. The machine should be able to protect itself from permanent damage if it brought too close to the magnet."* This Board does not agree with argumentation brought forward by Appellant when they state *"The requirement that the gaussmeter is on during the procedure is not mentioned in the tender document."* The tender dossier, also, does not mention that it is allowable for the safety mechanism to be switched off during use .

d) References made to the floor tape and brakes of the machine are deemed irrelevant, superfluous and outside scope.

e) Final consideration is now given to the Technical Literature submitted by Appellant, with specific reference to the user manual, which on more than one occasion mentions that the gauss meter is to be switched off before any clinical procedures. This Board, therefore, agrees with the Evaluation Committee, that such action will make the alarm and safety mechanism to be irrelevant in case of need and when actually required.

Hence, this Board does not uphold the Appellant's grievances.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides:

a) Does not uphold Appellant's Letter of Objection and contentions,
b) Upholds the Contracting Authority's decision in the recommendation for the award of the tender,
c) Directs that the deposit paid by Appellant not to be reimbursed.

Mr Kenneth Swain **Chairman**	**Dr Vincent Micallef** **Member**	**Ms Stephanie Scicluna Laiviera** **Member**