

PUBLIC CONTRACTS REVIEW BOARD

Case 1898 – CT2364/2022 – Supplies - Tender for the Supplies of Implantable Bone Conduction Hearing Aids

1st August 2023

The Board,

Having noted the letter of objection filed by Mr Richard Brook acting for and on behalf of Cochlear Austria GmbH, (hereinafter referred to as the appellant) filed on the 31st May 2023;

Having also noted the letter of reply filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 8th June 2023;

Having heard and evaluated the testimony of the witness Mr Daniel Rhodin (Representative of Cochlear) as summoned by Mr Dejan Mudrin acting for Cochlear Austria GmbH;

Having heard and evaluated the testimony of the witness Ms Jacqueline Busuttill (Member of the Evaluation Committee) as summoned by Dr Alexia J Farrugia Zrinzo acting for Central Procurement and Supplies Unit;

Having heard and evaluated the testimony of the witness Mr Arthur Wander (Representative of Medel Austria) as summoned by Dr John L. Gauci acting for Prohealth Ltd;

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 sitting of the 20th July 2023 hereunder-reproduced.

Minutes

Case 1898 – CT 2364/2022 – Supplies – Tender for the Supplies of Implantable Bone Conduction Hearing Aids

The tender was issued on the 3rd February 2023 and the closing date was the 7th March 2023. The estimated value of the tender, excluding VAT, was € 840,000.

On the 31st May 2023 Cochlear Austria GmbH 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 not technically compliant.

A deposit of € 4,200 was paid.

There were three (3) bids.

On the 20th July 2023 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Mr Lawrence Ancilleri and Ms Stephanie Scicluna Laiviera as members convened a virtual public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Cochlear Austria GmbH

Mr Daniel Rhodin	Representative
Ms Marlene Berthold	Representative
Mr Dejan Mudrin	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Marika Cutajar	Chairperson Evaluation Committee
Ms Jacqueline Busuttil	Evaluator

Preferred Bidder – Prohealth Ltd

Dr John Gauci	Legal Representative
Mr Mark Bondin	Representative

Department of Contracts

Dr Mark Anthony Debono	Legal Representative
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Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and invited submissions. He noted that the grievances and replies were clear what the appeal was about.

Mr Dejan Mudrin Representative for Cochlear Austria GmbH said that he was the Regional Development Manager for Cochlear and that the Appellant should not have been disqualified on the basis that they put in a separate claim for the battery compartment since both products offered in the tender have separate compartments which need air holes. It is unclear how the competitor claims that IP 54 has the same features. In fact, their literature through an asterisk indicates that the product allows limited ingress of water and dust which is not acceptable and contrary to IP standards.

Dr Alexia Farrugia Zrinzo Legal Representative for the Central Procurement and Supplies Unit (CPSU) referred to tender specifications 2.14 which states that the instrument has to be water and dust resistant.

Dr John Gauci Legal Representative for Prohealth Ltd said that the issue was about exclusion. By its own admission Appellant accepts that its offer does not meet the IP54 requested in the tender. Any doubts were further dispelled after Clarification 1 was published. The answers refer to the instrument as a whole. This appeal is unnecessary as if there were any doubts Appeal had recourse to Regulation 262 for a precontractual remedy. The appeal should be rejected.

Mr Daniel Rhodin (PP 97097375 – Sweden) called to testify by the Appellant stated on oath that he is a Senior Production Manager. Through a screenshot he demonstrated instruments IP52 which protects from dust and water ingress and IP57 which protects the electronics from water ingress. Their use and the protection afforded is clearly shown in the manual. It is surprising that the clarification speaks of the whole product because there is the possibility of water entry. The Medel

model offered by the preferred bidder states that limited ingress is permitted – this contradicts what is required and contrary to the tender which does not allow it. If IP 54 refers to the sound processor as a whole then neither bidder is compliant.

In reply to a question from Dr Farrugia Zrinzo witness said that he was not involved in the preparation of the tender and was not aware of the clarification.

Questioned by Dr Gauci, witness said that for some 20 years he has been an engineer in medical devices. He has been with Cochlear involved in sound processors development for five years. He was familiar with IP standards which focus on hazards and are judged by international bodies. Ingress is judged by well defined international tests. Clarification by the Contracting Authority stated that no water ingress is allowed and therefore overrides IP54.

Ms Jacqueline Busuttill (482872M) called as a witness by the Authority stated on oath that she is a Lead Audiologist and was one of the evaluators. The evaluators followed specification 2.14 and the documents submitted in reaching their decision. The IP rating requested was 54 and one bidder did not meet this requirement. The clarification which was published on the ePPs and available to all was sent to confirm that the unit offered included all the parts.

Questioned by Dr Gauci witness said that IP54 refers to the whole device including the battery and that the clarification confirmed this. The preferred bidder met this standard.

Mr Arthur Wander (PP U2276442 – Austria) called as a witness by Prohealth Ltd stated on oath that he was an employee of Medel Austria as a development engineer in implant systems. He was familiar with waterproofing standards which lay down protection against solids and water ingress – there were varying standards to test these. In IP54 the number 4 relates to fresh water ingress at certain splash strength situations so as not to influence their correct operation. The number 5 relates to dust ingress. The standards required in the bid were satisfied. The asterisk referred to by the Appellant refers purely to standards and not to water ingress.

When questioned by Mr Mudrin what limited water ingress referred to, witness replied that limited ingress is relevant for the whole device.

This concluded the testimonies.

Mr Mudrin said that the statement by Medel completely contradicts the clarification sent on the website – this disqualifies the preferred bidder. Cochlear has a superior IP rating, 57 as against 54 offered by the preferred bidder, and should not have been disqualified.

Dr Gauci said that evidence has been heard that objectors bid was not compliant; devices had to be compliant to IP54. Notwithstanding the clarification objector submitted its offer which is of an inferior standard. It is not up to the objectors to decide on their offer and they must conform to the law. The Authority would be acting outside its terms if it did not exclude Cochlear. The asterisk on the website is an explanation of what the IP stands for. The preferred bidder is fully compliant and the decision should be confirmed.

Dr Leon Camilleri Legal Representative for the CPSU said that Cochlear's grievance is that their product is compliant although they tried to raise further grievances at the hearing. The tender documents requests IP54 and with a further clarification that referred to the whole. The technical specifications are clear – the rating should cover all the device. The Evaluation Committee respected this as indeed did the preferred bidder. If objector had doubts there was a remedy available. The evaluation should be confirmed.

There being no further submission the Chairman thanked the parties and declared the hearing closed.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 20th July 2023.

Having noted the objection filed by Cochlear Austria GmbH (hereinafter referred to as the Appellant) on 31st May 2023, refers to the claims made by the same Appellant with regard to the tender of reference CT2364/2022 listed as case No. 1898 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Mr Dejan Mudrin

Appearing for the Contracting Authority: Dr Leon Camilleri & Dr Alexia Farrugia Zrinzo

Appearing for the Preferred Bidder: Dr John L. Gauci

Whereby, the Appellant contends that:

- a) Tender requirement: Specification 2.14 - The IP requirement specified in Specification 2.14 was for a minimum of IP54 water and dust resistance.
- b) Our Offered Product: - The Cochlear Osia 2 Sound Processor, with battery compartment excluded, is dust and water resistant to level IP57 of the International Standard IEC60529. The Osia 2 Sound Processor with Aqua+ is water resistant to level IP68 of the International Standard IEC60529 when used with LR44 alkaline or nickel metal hydride disposable batteries.
- c) Our conclusion - Specification 2.14 is satisfied by our Offered Product. Therefore, the statement that 'The item offered does not satisfy specification 2.14' is incorrect. With an IP57 rating, the Offered Product fully complies with the technical specification (IP54) laid out in point 2.14. Cochlear is the only active bone conduction producer that transparently reports IP rating with battery compartment included and excluded. ZN-air batteries need air for their function and therefore IP rating consequentially reduces. This goes for all producers except all producers are not disclosing this clearly in their features claims. This leads to false impression that competitive product has overall higher IP rating which is incorrect, and in fact, the opposite is true. Our product, excluding battery compartment, has higher IP rating (IP57) compared to competitive

product (IP54) also excluding the battery compartment. Whereas we have no information which IP competitive product has with ZN-air battery compartment included.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 8th June 2023 and its verbal submission during the virtual hearing held on 20th July 2023, in that:

- a) CPSU respectfully submits that the objector's grievance is unfounded since, as concluded by the evaluation committee, the product it offered clearly did not meet the technical criteria as established in the tender. Specification 2.14 requested a: Minimum of IP54 water and dust resistance. The tender deals with the whole product and does not distinguish between any parts of the same product such as excluding the battery cavity.
- b) This was further clarified before closing time for offers when a request for clarification was (sic) made by an interested party who asked: *"Point 2.14 of the technical specification states that the processor must have a minimum IP rating of 54 water and dust resistance. Kindly confirm that this is referring to all the compartments and cavities of the processor including battery compartment altogether."*
- c) The answer to the above quoted question was clear and unambiguous: *"This refers to the processor as a whole."*
- d) At evaluation stage, the evaluation committee asked the objector for a clarification on the IP rating of its offered product and the answer was: *"We hereby confirm that the Osia 2 sound processor is protected against failure from exposure to water and dust. It has achieved an IP57 rating (excluding battery cavity) and is water resistant, but not waterproof; with the battery cavity included the sound processor achieves an IP52 rating."*
- e) At publication and clarification stage the technical specification relating to the IP rating were clear and unambiguous and if the objector had any difficulty with such specification including the battery compartment, as it is giving the impression in the objection letter, it should have resorted to the procedure established in regulation 262 of the Public Procurement Regulations.
- f) Since the procedure established in article 262 was not resorted to and the specifications were thus accepted as published, the specifications had to be rigorously followed by the evaluation committee and as a matter of established fact, the product offered by the objector did not meet the requirement of having a minimum IP rating of IP54 as a whole.
- g) The decision of the evaluation committee was therefore justified, correct and in line with what is expected from them.

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 in their entirety.

- a) The Board opines that requirement 2.14 of Section 3 – Specifications of the tender dossier was clear and unambiguous when it stated that “*Minimum of IP54 water and dust resistance*”.
- b) This was further re-enforced through a clarification which was issued **during** the tendering process (bold emphasis added), therefore it was available to all economic operators participating in the tender procedure, that the specification “*refers to the processor as a **whole***”. (bold emphasis added)
- c) The appellant, on an *ex admisissis* basis, declared through a clarification request from the evaluation committee, that his product “*with the battery cavity included the sound processor achieves an IP52 rating.*”
- d) Even though, this Board has already stated that in its opinion specification 2.14 was clear and unambiguous, should the Appellant have felt that the technical specification was in any way counter productive to free competition and / or technically was not possible, it had other remedies to pursue. Reference is made to regulation 262 of the Public Procurement Regulations (“PPR”)
- e) With regards to the “*” issue present in the preferred bidder’s technical literature, this Board opines that:
 - i. Such a grievance was not present in the original letter of objection which was filed on 31st May 2023 by the Appellant. Consequently such a grievance cannot be presented at this stage as it contravenes regulation 270 of the PPR which states “*.....may file an appeal by means of an objection before the Public Contracts Review Board, **which shall contain in a very clear manner the reasons for their complaints.***” (bold & underline emphasis added)
 - ii. None-the-less, no sufficient proof was presented to cast doubt on the evaluation done by the evaluation committee.

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 Charles Cassar
Member

Ms Stephanie Scicluna Laiviera
Member