PUBLIC CONTRACTS REVIEW BOARD

Case 2166 – 020-4008/24 CPSU2330/24 – Supply of Neonatal SpO2 Adhesive sensors – S-Senso-027 – Lot 2

3rd November 2025

The Board,

Having noted the letter of objection filed by Dr Douglas Aquilina, Dr Mark Attard Montalto and Dr Samira Briffa on behalf of Attard Montalto & Aquilina Advocates acting for and on behalf of Drugsales Limited, (hereinafter referred to as the appellant) filed on the 11th July 2025;

Having also noted the joint letter of reply filed by Dr Alexia Farrugia Zrinzo and Dr Leon Camilleri acting for the Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 21st July 2025;

Having heard and evaluated the testimony of the witness Ms Winifred Buhagiar (Member of the Evaluation Committee) as summoned by Dr Douglas Aquilina acting for the Appellant;

Having heard and evaluated the testimony of the witness Mr Igor Persianov (Representative of Masimo Technology) as summoned by Dr Douglas Aquilina acting for the Appellant;

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 14th October 2025 hereunder-reproduced.

Minutes

Case 2166 020-4008/24 CPSU2330/24 – Supply of Neonatal Sp02 Adhesive Sensors – S-SENSO-027 Lot 2.

The tender was issued on the 1st of October 2024, and the closing date was the 22nd of October 2024.

The estimated value of the tender, excluding VAT, was €51.744.00

On 11th July 2025 Drugsales Limited. (Comp. reg. no. 1023-9222) lodged an appeal against Central Procurement and Supplies Unit (CPSU) – the Contracting Authority, and the Recommended Bidder, Procare Ltd. in accordance with Regulation 270 of the Public Procurement Regulations.

A deposit of €550.00 was paid.

There were Three bids.

On the 14th of October 2025, the Public Contracts Review Board (PCRB), composed of Mr Kenneth Swain as Chairman, Mr Keith Victor Grech and Mr. Lawrence Ancilleri, as members, convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Drugsales Ltd. (1023-9222).

Dr Douglas Aquilina – Legal Representative.

Ms Giulia Attard Montalto – Company Representative.

Mr Claudio Martinelli – Company Representative.

Mr Reuben Demanuele – Company Representative.

Contracting Authority – Central procurement and Supplies Unit (CPSU).

Dr Leon Camilleri – Legal Representative.

Ms Veronica Sytnyk – Legal Trainee.

Mr. Juan Zarb-Cousin – Chairperson.

Ms. Jacqueline Borg – Secretary.

Ms. Winifred Buhagiar – Evaluator.

Recommended Bidder – ProCare Ltd.

Dr Robert Galea – Legal Representative.

Mr Pierre Calleja – Director.

Opening Statements.

Mr. Kenneth Swain, Chairman of the Public Contracts Review Board (PCRB), welcomed the parties present: the Appellant, Drugsales Limited; the Contracting Authority, Central Procurement and Supplies Unit (CPSU); and the Recommended Bidder, ProCare Ltd.

Initial Submissions.

Initial Submissions by Dr. Douglas Aquilina (Appellant).

Dr. Aquilina stated that the products in question are Neonatal SpO_2 sensors that are attached to monitors owned by the hospital. The tender was specific and requested sensors using the same technology as the monitors — namely, Masimo technology. The awarded bidder submitted copies of counterfeit products. The Contracting Authority sometimes referred to the products as technically compliant or functionally equivalent. However, if a product is claimed to be functionally equivalent, there must be proof, in accordance with the law, that it meets the same standards as Masimo. If the technology was copied, that would amount to infringement — a completely different case.

Initial Submissions by Dr. Leon Camilleri (Contracting Authority).

Dr. Camilleri stated that the Evaluation Committee had carried out its assessment according to the parameters of the law and concluded that the product offered by the recommended bidder was compliant with the tender requirements.

Initial Submissions by Dr. Robert Galea (Recommended Bidder).

Dr. Galea, representing ProCare Ltd, maintained that the product offered was compliant with the specifications requested, and that the award granted to ProCare was justified.

Witness.

Ms. Winifred Buhagiar (ID No. 24064M) *– Summoned by Dr. Aquilina.*

Dr. Aquilina stated that the tender in question was CPSU 2330/24, Lots 1A, 1B, and Lot 2. Ms. Buhagiar had requested SpO_2 monitors with Masimo technology or compatible alternatives. Dr. Aquilina noted that the tender required sensors that fit Lot 1A and 1B – 4000 with Masimo technology sets, and Lot 2 to fit monitor RD set RAD 57/59.

Ms. Buhagiar confirmed that the products requested had to fit the monitors and cables already owned. The request was specifically for Masimo technology. The tender referenced specific product codes, LNCS Neo Code 2329, LNCS Neo PT 2330, and RD set 4003, which were the codes corresponding to Masimo probes. The recommended bidder offered compatible products. No pre-submission clarifications were made. The recommended bidder submitted Masimo samples, and Ms. Buhagiar, a nurse rather than a technical expert, tested the sample on a baby and confirmed it worked. Ms. Buhagiar was asked to produce the literature where the recommended bidder claimed to have submitted Masimo technology, and this was shared with all parties.

Dr. Aquilina emphasised that in the bid, there was 'compatible with Masimo'. Ms. Buhagiar testified that she tested the samples by connecting the cables to the monitors and confirmed they functioned correctly on a baby, as with the previous SpO_2 sensors.

The Chairman intervened, and Ms. Buhagiar stated that she was a Charge Nurse at the MPICU. Describing the timeline of events, she said she read the literature, requested samples, tested them, and was satisfied with the results.

Dr. Aquilina requested proof of the results. Ms. Buhagiar stated that the oxygen level of 97% remained the same when tested with the sample probe. The test was conducted on a baby in the intensive care unit, using a ventilator and an incubator; however, she did not recall whether the baby was in a state of low perfusion.

Dr. Aquilina mentioned that the refusal letter addressed to Drugsales Ltd. stated that their product was not technically compliant. Ms. Buhagiar maintained that the Drugsales product was compliant.

The Chairman read the rejection letter, stating that 'a cheaper and technically compliant offer was being recommended'; however, the Drugsales offer was technically compliant as well.

Cross-Examination by Dr. Leon Camilleri.

Ms. Buhagiar confirmed that she has worked in the Neonatal Intensive Care Unit for many years. The tender specifications stated, 'to fit monitor or pulse of the meter with RD set with Masimo technology set'. The product offered by the recommended bidder fit those specifications. Referring to the functional specifications 1.1 of the technical offer form, Ms. Buhagiar stated that the monitor displayed the heart rate and SpO_2 in the same way as the previous cable — it was compatible.

Cross-Examination by Dr. Robert Galea.

Ms. Buhagiar explained that she had requested the samples after reading the product literature, as it was a new product. She confirmed that she was satisfied with the product and found it compliant with the monitors.

Witness.

Mr. Igor Persianov (Licence No. 23363201F47) *– Summoned online by Dr. Aquilina.*

Mr. Persianov, a Senior Manager for Masimo in Europe, explained that the codes requested in the tender could be used for both neonatal and adult patients. The sensor is attached to the patient's finger, foot, or hand, transmitting information via cable to a socket on a Masimo board. Masimo monitors are equipped with Masimo technology across all models. The 4000 -monitor is manufactured by General Electric (GE), while the RAD monitor is a Masimo-manufactured model.

Mr. Persianov explained that the technology relies on a combination of cable sensors and the internal board. If one component is replaced, the technology's performance is compromised. The system's accuracy provides clinicians with reliable readings of oxygen saturation, pulse rate, and diffusion readings. Masimo offers two accuracy levels — one without motion and one with motion and low diffusion — both essential for intensive care patients.

Accuracy values are listed in the reference tables of the data sheet. Masimo, a U.S.-based company, holds several patents published on its website. While Masimo licenses its technology to various medical companies, it does not grant licenses for the manufacture of sensors.

Dr. Aquilina asked whether the company Sino-K, whose products were submitted by the recommended bidder (codes SP1015F, SP1815F, SP1015E), was one of Masimo's licensed partners.

Mr. Persianov replied in the negative. He explained that although Sino-K claimed compatibility, Masimo could not verify the accuracy of those products. Masimo technology maintains an accuracy of 1.5%, supported by data submitted to relevant authorities.

Dr. Aquilina mentioned that the Contracting Authority had tested the Sino-K sensors by simply plugging them into the monitor and observing a reading.

Dr. Galea objected, arguing that Dr. Aquilina was soliciting an opinion and not following proper procedure.

The Chairman upheld the objection.

Dr. Aquilina then presented the technical specifications of the RD Set and LNCS series. Mr. Persianov explained that these documents detail verified accuracy metrics confirmed by authorities.

Dr. Galea interrupted, noting that the witness was unaware of which documents were before the Board and that he was an independent witness.

Mr. Swain asked Dr. Aquilina to direct the witness accordingly.

Dr. Aquilina asked Mr. Persianov whether he was familiar with the Instructions for Use (IFUs). Mr. Persianov confirmed that these documents are publicly available online and outline the use of different sensor models. The two relevant documents are titled *RD Set Series* and *MLNCS Series*. Codes

LNCS Neo 2329 and 2330 fall under the MLNCS IFU, while RD Set Code 4003 falls under the RD Set Series.

Dr. Aquilina referred to page 6 of the document.

The Chairman intervened, asking Mr. Persianov about the documents, and he confirmed that he had them in front of him.

Dr. Aquilina referred to page 3 of the LNCS document regarding sensor accuracy ratings. Mr. Persianov explained that Code 2329 LNCS Neo corresponds to 3–40 kg, and Code 2330 LNCS Neo PT is listed in the final column.

Regarding the RD Set Series on page 6, these parameters appear in the penultimate column. He added that these accuracy values were established through laboratory testing and blood sampling. Masimo technology is 30 years old, supported by hundreds of independent publications, and additional validation studies are ongoing in the United States.

Cross-Examination by Dr. Leon Camilleri.

Mr. Persianov, a Senior Manager at Masimo and a PhD-qualified medical doctor in radiology, acknowledged that there are other products on the market that can connect to the monitor—4000 and function with different technology. He was not familiar with the product offered by ProCare Ltd but was informed that such sensors existed.

Re-Cross Examination by Dr. Douglas Aquilina.

Dr. Aquilina asked Mr. Persianov whether Sino-K products used Masimo technology. Mr. Persianov stated that, from an engineering standpoint, the technology was not Masimo's. Masimo's technology is patented, and Sino-K does not have rights to use it.

Final Submissions.

Final Submissions by Dr. Douglas Aquilina (Appellant).

The tender specifications required that the sensors could be plugged into the monitors and must use the same technology, specifically Masimo models, as stated in section 1.1, which requested neonatal sensors with Masimo technology. Clauses 2.6 and 2.7 identify particular product codes. The tender explicitly requested Masimo products, as these were tested and compatible with the hospital's monitors. It is insufficient to rely solely on similar readings under ideal conditions.

When a bidder offers a functionally equivalent product, it must be proven that the product produces identical results. ProCare Ltd. did not demonstrate such accuracy, particularly in low-perfusion scenarios; it merely claimed that its sensors were Masimo compatible.

The tender requested a Gold Standard Masimo product, the same technology licensed to companies like Philips and General Electric, yet a foreign company without a Masimo licence submitted a product claiming compatibility. The product is counterfeit, as Sino-K did not develop its own technology but copied Masimo's. If Sino-K had its own technology, comparative results could have been provided. The CPSU was obliged to verify the product.

The Contracting Authority, incites in the general rules, that when one asks for a particular brand, in our case the product codes and he quotes:

'The Contracting Authority will accept equivalent brands or labels; however, it is the responsibility of the respective bidders to prove that the standards, brands or labels are equivalent to those requested by the Contracting Authority'.

There was no proof that the results were equivalent. The fact that the sample appeared to work under normal conditions is not sufficient proof.

The tender explicitly requested Masimo products and codes, and there was no clarification or pre-contractual remedy. ProCare Ltd. declared its product compliant in section 1.1, when it falsely claimed to be submitting sensors with Masimo technology. Even in clauses 2.6 and 2.7, the required codes were not provided. They could have at least proven functional equivalence.

Ultimately, ProCare Ltd. did not offer the same standard as requested, and it is unacceptable that a product of lower standard was awarded the contract. Dr. Aquilina referred to Case VII Verg 20/15 before the Düsseldorf Court, where a patented medicinal product (Pregabalin) was unlawfully copied during the patent period. Under clause 414, Regulation 608/2013, counterfeit products cannot legally be placed on the market. Masimo did not license its technology to Sino-K, yet Sino-K claims compatibility.

Final Submissions by Dr. Leon Camilleri (Contracting Authority).

Dr. Camilleri acknowledged that the burden of proof normally rests with the bidder; however, once the appeal was lodged, the burden shifted to the appellant, who was contesting the decision. The witness supported the appellant's product but admitted having no knowledge of the recommended bidder's product.

The manufacturer of the monitor can only guarantee its own sensors and cannot comment on untested third-party products. Therefore, the witness could not testify about the ProCare Ltd. sensors.

Clause 1.0 of the tender requested a product that 'serves the function of Masimo technology', while the technical specifications required sensors 'to fit monitor – with Masimo technology set'. Witness Ms. Buhagiar tested the sensor on an intensive care baby and confirmed identical readings to those of the previous sensor, after verifying compliance on paper.

The appellant claimed that the winning bidder failed to match Masimo's specifications; however, the specifications were defined by the Contracting Authority, not the appellant. Since the recommended bidder's product complied with the published specifications — both on paper and in practice — the Evaluation Committee had no reason not to recommend it.

The proper comparison, Dr. Camilleri stressed, is between the bidder's offer and the tender's requirements — not between competing bidders.

Final Submissions by Dr. Robert Galea (Recommended Bidder).

Dr. Galea stated that:

1. The online witness did not know which documents were presented to the Board.

2. The witness provided a licence number without submitting a copy of the licence or confirming his identity.
3. The witness appeared to work for an entity called Masimo, without confirming the company's name, his position, or the legal entity he represented.

No one could confirm his authority to represent Masimo.

Regarding the merits, Dr. Galea argued that the Contracting Authority requested samples after evaluation. Scientifically, there is the concept of a 'control experiment'. The witness (Ms. Buhagiar) did not simply rely on visual readings — she used the product on a baby who had already been monitored, and the readings matched exactly. This was '100% confirmation that the product functions exactly the same', and thus, the appellant could not claim incompatibility.

The appellants, Dr. Galea added, were ignoring the reality of an open market. According to clause 5.6 of the General Rules, the Contracting Authority cannot request a specific brand name product unless it is a direct order.

The witness admitted that the technology is complex and highly engineered but did not state that the ProCare product was not equivalent. There was concrete proof that the product matched previous readings, and no evidence was presented to prove incompatibility.

The Contracting Authority requested a product 'to fit', meaning it had to be compatible with the existing monitors. To require a specific brand would contravene European regulations on the free movement of goods.

Conclusion of the Hearing.

With no further submissions, Mr. Kenneth Swain thanked all parties and formally concluded the session.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 14th October 2025.

Having noted the objection filed by Cherubino Limited (hereinafter referred to as the Appellant) on 11th July 2025, refers to the claims made by the same Appellant with regard to the tender of reference 020-4008/24 CPSU 2330/24 – Lot 2 listed as case No. 2166 in the records of the Public Contracts Review Board.

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

Appearing for the Recommended Bidder: Dr Robert Galea

Whereby, the Appellant contends that:

a) ***First grievance – Products offered by the recommended bidder are non-compliant***

The tender document is very clear in requiring Neonatal sensors with Masimo technology.

It appears that the product offered by the recommended bidder does not have Masimo technology, is not licensed or approved to use Masimo technology and does not even claim to have "Masimo technology". The product offered by the recommended bidder does not have and cannot have Masimo technology. It is simply using a similarly confusing name of "Masimo".

Therefore it is evident that the recommended bidder's product is technically non-compliant with the tender requirements and should have been rejected.

It is be noted that Masio technology is proprietary technology in this sector that has significant medical justifications and benefits, and ensures accurate readings and compatibility with the rest of the system. Non-Masimo sensors have not been approved, whether by Masimo or by any regulatory authorities, as being compatible and usable as part of the Masimo system. In fact, the Masimo system is approved for use solely in conjunction with Masimo sensors. Non-Masimo sensors cannot be used since this would be a breach of use of the approved system and an unauthorized alteration of the system. Furthermore in practice there is no guarantee whatsoever that non-Masimo sensors will be compatible with the system or will produce clinically reliable results with the system. Non-Masimo sensors may also disrupt or damage the rest of the system.

It is also to be noted for all intents and purposes that the requirement for Masimo technology was clear in the tender documents and no contestation of whatsoever nature was made with respect to this mandatory technical requirement. Should there have been any contestation as to this requirement, appropriate remedies needed to be taken such as clarifications and remedies in terms of Regulation 262, which remedies were not taken, and therefore the technical specifications need to be adhered to in full. This as confirmed in several cases before this Board and the appellate court. Therefore it is evident that the product offered by the recommended bidder is technically non-compliant and should have been rejected.

b) ***Second grievance – Product offered by Drugsales Limited is compliant***

In the letter dated 1 July 2025, the contracting authority informed Drugsales Ltd that its offer was not technically compliant since a cheaper and technically compliant offer is being recommended. Therefore the offer of Drugsales Ltd was deemed technically non-compliant simply due to the fact that there was an allegedly cheaper and technically compliant offer. This is factually and legal incorrect, and appears to be an error of expression by the contracting authority. The fact that there

may or may not be a cheaper and technically compliant offer which is being recommended for award, simply means that the offer made by Drugsales Ltd was rejected in favour of a cheaper offer. It does not in any way mean or imply that the offer of Drugsales Ltd "not technically compliant."

The offer of Drugsales Ltd was in fact fully technically compliant with the tender specifications.

In fact, the contracting authority brought no reason to explain why the offer of Drugsales Ltd could be considered technically non-compliant, other than the existence of a cheaper offer from another bidder.

Therefore the offer of Drugsales Ltd is to be fully reintegrated in the evaluation process, should the evaluation process be so re-opened.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 21st July 2025and its verbal submission during the hearing held on 14th October 2025, in that:

a) ***First grievance – Products offered by the recommended bidder are non-compliant***

CPSU primarily submit that the onus of proof lies on the objector to prove its claims. CPSU submits that this grievance is unfounded in fact and at law for the following reasons The product of the recommended bidder has been evaluated and compared to the technical specifications published in the tender and the evaluation committee was convinced that the product recommended is technically compliant. Moreover, the product of the recommended bidder was tested on neonatal children and the product was functional compliant and satisfies its intended use. Moreover, and without prejudice to the above, clause 5.6 of the General Rules Governing Tenders provides that: *"Where in the tender document a standard, brand or label is quoted, it is to be understood that the Contracting Authority will accept equivalent standards, brands or labels. However, it will be the responsibility of the respective bidders, at tendering stage, to prove that the standards, brands or labels they quoted are equivalent to the standards, brands or labels requested by the Contracting Authority."*

b) ***Second grievance – Product offered by Drugsales Limited is compliant***

CPSU on behalf of the evaluation committee has never informed the objector that its offer was not technically compliant. CPSU can confirm that the offer of the objector was deemed as technically compliant however, was not the cheapest. The letter of rejection states that: *The main reason/s why your procurement proposal was non-compliant is/are as follows: Reason for rejection: Lot 1 and 2: A cheaper and technically compliant offer is being recommended.* Lack of compliance is not necessarily technical; it can be administrative or financial. Technical compliance was at no point mentioned. Although CPSU acknowledged that the term 'non-compliant' was not the ideal term to be used, the reason for rejection was clear and thus this grievance is frivolous.

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) The Board notes that the core dispute concerns whether the product offered by the recommended bidder satisfies the technical specifications set out in the tender, specifically regarding compatibility with monitoring systems using Masimo technology.

b) The Board observes that the tender specifications required that the neonatal SpO_2 sensors must be capable of being used with, and must function properly when connected to, the Masimo-based monitoring systems currently in operation within the contracting authority's neonatal care setting. The wording of the tender documentation, particularly the functional specifications, did not create an exclusive requirement for the supply of Masimo-branded sensors, but rather required sensors that would fit and function with a Masimo technology system.

c) In this regard, the Board recalls Clause 5.6 of the General Rules Governing Public Tenders, which provides that where a standard, brand, or label is referenced in a tender document, the Contracting Authority shall accept equivalent standards, brands, or labels, provided that the bidder demonstrates equivalence. Therefore, the key legal and technical question before the Evaluation Committee, and now before the Board, is whether the recommended bidder sufficiently demonstrated functional equivalence.

d) Based on the evidence presented, the Evaluation Committee conducted an assessment of the recommended bidder's product both on paper and through practical testing, including a clinical demonstration on neonatal equipment currently in use. The Board notes the testimony of Ms. Buhagiar confirming that when connected to the existing monitors, the recommended bidder's sensors produced accurate and stable readings in line with the expected clinical parameters, thus meeting the functional performance requirement expressed in the tender specifications.

e) Having reviewed the objection submitted by the Appellant, the Board finds no sufficient basis to conclude that the Evaluation Committee erred in determining that the product offered by the recommended bidder met the technical requirements as published in the tender documentation.

f) The Board also takes into consideration the Appellant's claim regarding proprietary technology and the possibility of patent infringement. While the Board acknowledges that matters relating to patent rights or alleged intellectual property infringement may carry regulatory and commercial implications, the Board must emphasise that such issues fall outside the jurisdiction of the PCRB, whose role is strictly limited to determining whether a tendering procedure has been carried out in compliance with procurement law and the tender documents. The Board does not adjudicate disputes relating to intellectual property rights or alleged counterfeit goods, and such claims may be pursued before the competent judicial fora if a party deems it appropriate.

g) Regarding the Appellant's second grievance, the Board notes the Contracting Authority's clarification that the Appellant's offer had been considered technically non-compliant, but was not

selected because another offer was found to be both technically compliant and cheaper. Although the terminology used in the rejection letter was not ideal, the Board is satisfied that the decision of the Contracting Authority was based on a lawful application of the most economically advantageous tender principle, and that no prejudice was caused to the Appellant.

h) In light of the above considerations, the Board finds that:
   - The product offered by the recommended bidder was rightly evaluated as technically compliant, having demonstrated compatibility and functional equivalence as required by the tender,
   - The evaluation process was conducted within the discretion afforded to the Contracting Authority,
   - No procedural irregularity or breach of procurement principles has been established by the Appellant.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides in relation to Lot 2:

a) To reject the appeal submitted by the Appellant, Drugsales Limited;
b) To uphold the decision of the Contracting Authority recommending the award of Tender 020-4008/24 CPSU 2330/24 (Lot 2) to the recommended bidder; and
c) To order that the deposit paid by the Appellant shall not be reimbursed.

Mr Kenneth Swain	**Mr Lawrence Ancilleri**	**Mr Keith Victor Grech**
Chairman	**Member**	**Member**