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PUBLIC CONTRACTS REVIEW BOARD

LETTER OF OBJECTION OF PROCARE LTD (C 71386)

21st November 2026

Ref: *CT2058/2026*

Subject: *FRAMEWORK CONTRACT FOR THE SUPPLY OF IFOBT AND CALPROTECTIN TESTING ON A PAY-PER-USE BASIS*

Dear Sir,

By means of this present letter ProCare Ltd (C 71386) [hereinafter referred to as 'the Objector'], of 42, Carmelina Court, No. 5, Triq E. B. Vella, Mosta, whilst making reference to the above captioned call for tenders, is hereby submitting a formal objection in relation to the same tender, more specifically in relation to the Decision dated 13th November 2026 (vide attached Doc A), whereby the Contracting Authority, namely the Department of Contracts, for the benefit of the final beneficiary being the Central Procurement and Supplies Unit (Ministry for Health and Active Ageing) [hereinafter referred to as the 'Contracting Authority'] indicated that the Objector's proposal was deemed as being *"technically non-compliant"*, specifically for the following given reasons:

"As per Section 3, Specifications, Clause 2.5, "All internal controls (minimum of two levels) and calibrators required for the duration of the contract period must be ready to use and are to be provided in sufficient quantities free of charge." The Bidder submitted Technical Documentation (Note 3), specifically the Instructions for Use (IFU) for the controls, titled "910873_FIT NS-Prime Control_IFU_Rev.2_20260701_DRAFT." The IFU states that the controls are lyophilized and therefore require preparation prior to use. Consequently, the controls cannot be considered "ready to use" as required under Clause 2.5.

Bidder failed to submit the required Declaration of Conformity (NOTE 3) for item "912587 - Wash Solution A" which is a CE-IVD marked product. A valid Declaration of Conformity for the product being offered must be provided as per Technical Offer under Section II (6.) and Clause 2.12 of Section 3 of the Technical Specifications. This requirement applies to items subject to the In Vitro Diagnostic Medical Devices Regulation (IVDR; Regulation (EU) 2017/746) and, during the applicable transition periods, the In Vitro Diagnostic Medical Devices Directive (IVDD; Directive 98/79/EC). As this requirement is classified as NOTE 3, it is non-rectifiable. Offer not technically compliant."

Whereas the Objector feels aggrieved by this decision, and its grievances, which are clear and manifest, consist of the following:

1. *About the existence of a clear error of fact on the part of the Contracting Authority in reaching the decision*

Whereas the reason which is being given by the Contracting Authority under the first (1st) heading for rejecting the offer made by the Objector is that allegedly, the Objector's offer is "

The IFU states that the controls are lyophilized and therefore require preparation prior to use. Consequently, the controls cannot be considered "ready to use" as required under Clause 2.5", which is understood to mean that the offer as made is deemed as being technically non-compliant.

Whereas in the humble opinion of the Objector, in this case this is a clear and manifest error of fact since the Objector did, in fact, submit an offer which was in line with what was required by the Contracting Authority. While it is not contested that the Contracting Authority required a

product that is 'ready to use', it cannot be stated that what the Objector provided does not satisfy this requirement. The argument that is being made by the Contracting Authority is that the controls are lyophilized (freeze dried into powder form, and subject to reconstitution upon hydration) and that as such, therefore, they cannot be deemed as 'ready to use'. With all due respect, such interpretation is not in line with what one could expect in the current scenario and setting where the devices are meant to be used.

Whereas as results from the technical documentation submitted, as surely analysed by the Evaluation Committee, the devices supplied by the Objector are such as to contain a full kit with all that is required for the purposes of utilising the controls, including all elements necessary to reconstitute the same, with minimal user intervention. As such, therefore, the kits as supplied are surely ready to use. Surely the Evaluation Committee could appreciated that no extra reagents are required in order to utilise the device in question, neither any third party material nor any dilution calculation. Definitely, therefore, the devices as such as to be considered as being 'ready to use'. To further make the items indeed 'ready to use', as will be elaborated further before this Honourable Board, the devices in question are such that when reconstituted, they are used directly in the relative equipment and are recognised by the analyser through an integrated barcode reader, making them, thus, ready to use.

Whereas of note is the fact that Clause 2.5 applies the same 'ready to use' criterion to both controls and even to calibrators. While the control is hereby being rejected due to the fact that it is lyophilised, the calibrator offered, despite being lyophilised, attracted no such opposition. This shows that the manner in which the tender was being evaluated lacked consistency.

Whereas as will be shown in the course of these proceedings, the interpretation and approach adopted by the Evaluation Committee is such as to be inconsistent, and, as such, flawed. Whereas this is being said due to the fact that the controls proposed by the bidder to whom the current contract has been awarded, while supplied in liquid form, require the operator to manually dispense drops into a sample cup every time the device is being use. Is this, therefore,

considered ready to use, when each and every run of the analyser requires specific steps to be taken by the operator, making the system, thus, not one which is ready to use?

Whereas an economic operators in the sector the Objectors can't but point out to the lack of consistency in approach, where in tender Tender document CT2398.2021 (attached Doc B, being extract from the said tender document), where it was required that "*15. Tender offer must include proportionate quantities (as dictated by the kit protocol supplied) of all accessory reagents, consumables, controls and calibrators* ***(Ready to use).***" the offer they made included reagents which were supplied lyophilised and needed reconstitution. This contract was awarded to them and is still being supplied to date!

Whereas primarily reference must be made to the Technical Specifications document – titled 'Technical Offer' – submitted by the Objector, wherein it was specifically declared that the unit in question is truly compliant in that it is 'ready to use'.

Whereas it must be pointed out that the Objectors submitted all the available documentation that could possibly be provided by the manufacturer with respect to the device in question. Consequently, the Objectors could in no manner provide further literature other than that which was provided. The declaration made by the Objector in the Technical Specifications document is the **only form of positive declaration** that could be provided by the Objector on such fact that the system is one that is ready for use, however, this was not questioned by the Evaluation Committee through the clarification process.

Whereas the Objector should not, therefore, be penalised merely because the standard format of the Technical Specifications sheets seems to use terminology that, apparently, leaves the Contracting Authority unsure as to how to evaluate the tender in question. Such requirement of the devices being 'ready for use' form part of the Technical Specifications. This is indeed a very dangerous scenario.

Whereas the device in question is clearly one which was 'ready for use' and as such, should not have been disqualified. This would have been different if the tender laid down other requirements, such as that controls must be supplied in liquid form and must not require reconstitution. However, as expounded infra, this could not be introduced as an added specification, *ex post facto*.

Whereas clearly the Evaluation Committee was exercising a discretion in determining whether the submitted proposal could be regarded as 'ready for use'. In this context, therefore, the fact that the Contracting Authority might have put forward an unsatisfactorily drafted tender document – as will be expounded infra – which seems to set down requirements which are themselves subject to interpretation, should not serve to operate against the bidder's possibility of having their offer considered.

Whereas furthermore, reference must at this point be made to Reg 53(6) of the Public Procurement Regulations which lay down that

> (6) Technical specifications shall afford equal access of economic operators to the procurement procedure and shall not have the effect of creating unjustified obstacles to the opening up of public procurement to competition.

In view of the fact that the controls used with the device as proposed by the Objectors is, as such, ready for use, the position assumed by the Evaluation Committee in the interpretation of the requirements renders such technical specification in breach of the above regulation. Again, a caveat must be made here; such rigour in the application of the requirement seems to be at the sole discretion of the Evaluation Committee which seems to apply such measure only as it deems fit; the Evaluation Committee opted to shift the goalposts and treat submissions differently, since, as stated, while it concluded that the controls proposed by the Objectors were not 'ready for use', yet, it was satisfied with the controls proposed by the chosen bidder, where the controls require manual involvement with each use.

Whereas also, as stated, the Objector made a declaration that the technical specifications indicated should be deemed as sufficient for the purposes of the tender in question. In making such declaration, the bidder is taking up a serious undertaking with respect to the contracting authority. This was not considered at all, and in view of this declaration, the least that the Evaluation Committee could do was request a clarification as it opted to do elsewhere.

Whereas the documents submitted during the tender process as well as the declarations made by the bidder form the very basis of the eventual contract between the successful bidder and the Contracting Authority. Such contract, is based, *inter alia*, on the declarations made by the bidder at tendering stage, and consequently, the fact that the bidder would have confirmed that the Technical Specifications are fulfilled should not be taken lightly.

Whereas in view of the above reasons, such decision is clearly unfounded, and the Objector is of the opinion that it should be quashed.

2. ***About the obligation of the Contracting Authority to act within the confines of the requirements***

Whereas reference is to be made to Regulation 242 of the Manual of Procedures[1] which speaks of the importance of the fact that the Contracting Authority provides clear reasons for any decisions taken. In this present case, not only is the motivation dubious in that it is clearly arbitrary and subjective (as stated above), but there is a scenario where the offer as made was not evaluated in terms of the applicable technical specifications, but instead, 'new specifications' were subliminally introduced.

Whereas clearly this is in direct breach of the very basic principles governing the award of public contracts, and also manifestly in breach of the principle of natural justice regarding the giving of reasons for decisions as will be expounded hereunder.

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[1] Manual of Procedures, Public Procurement Regulations, 2016 (SL 174.04), Policy Development and Programme Implementation Directorate, Version 1.1 – Department of Contracts, Ministry for Finance.

Whereas this is not something which is merely logical, not something which is merely desirable, not something which the Objectors alone are stating, but it is also stated by the European Commission[2] which states that:

> *The first task of the Evaluation Committee is to check all tenders to ensure that they are 'compliant', in other words that they have followed the instructions to tenderers to the letter.*

Whereas this basically also means that the Evaluation Committee is also to evaluate the offers made against the requirements that would have been communicated to bidders and not against additional requirements which would not have been so communicated, as happened in this case.

Whereas this is being stated because, as stated supra and as will result in the course of these proceedings, the control offered by the Objectors is such as to be used immediately without using anything from any external system, and thus, is 'ready for use'. This is different from the scenario in the case of the offer which was awarded the contract, since, as shown above, the system is not ready for use and requires user input with every single use. However, it is has clearly resulted, at this stage, that the Evaluation Committee concluded that the device proposed by the Objectors is not 'ready for use' as it is not in liquid form.

Whereas, however, it is up to the Evaluation Committee, at this stage, to show that the technical specifications required the control not only to be 'ready for use' but also to be in liquid form. While this was not required in the technical specifications of the present tender, the Evaluation Committee has, nevertheless, reached the conclusion that merely because the controls needed reconstitution, they could not be deemed as 'ready for use'.

Whereas once that it is determined that the instructions – including the requirements set out in the technical specifications – have been complied with, **the Evaluation Committee cannot, *sua sponte*, introduce 'further criteria'** on the basis of which the tender is then adjudicated.

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[2] Public Procurement Guidance for Practitioners on the avoidance of the most common errors in projects funded by the European Structural and Investment Funds, European Commission, Directorate-General for Regional and Urban policy, European Union 2015.

Whereas the Directive 2014/24/EU[3] on Public Procurement, the Public Procurement Regulations (S.L. 174.04), and the General Conditions for Supply Contracts[4] define 'Technical Specifications' as

> *in the case of supply contracts, the specification in a document* ***defining the required characteristics of a product or a service****, ...* [emphasis added]

Whereas Regulation 53(1) of the Public Procurement Regulations (S.L. 174.04) states that

> *The technical specifications* ***shall*** *be set out in the procurement documents and these shall lay down the characteristics required of a works, service or supply.* [emphasis added]

Whereas this reflects Article 42(1) of Directive 2014/24/EU on Public Procurement

> *The technical specifications as defined in point 1 of Annex VII* ***shall*** *be set out in the procurement documents.* ***The technical specification shall lay down the characteristics required of a works, service or supply****."* [emphasis added]

Whereas from this, the Objector humbly submits that it logically follows that the existence and availability of technical specifications is not an option but an *ad validitatem* requirement of a tender for a supply contract, and it is on the basis of such technical specifications that an offer is to be made and subsequently adjudicated and not on other extraneous and arbitrary factors.

Whereas in view of the reason given for the refusal one naturally refers to the Technical Specifications, which lay down the technical requirements of the devices in question.

Whereas at this point it is important to make reference to the intrinsic nature and function of technical specifications. Technical specifications are at the very centre of the public procurement process since they make several crucial matters possible:

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[3] Of the European Parliament and of the Council of 26 February 2014.

[4] v2.3, Department of Contracts, May 2018.

(i) They lay down what the Contracting Authority requires;

(ii) They indicate what a potential supplier should seek to;

(iii) And, fundamentally, they establish the qualitative standard against which any offer made is to be evaluated.

Whereas, consequently, it is through the proper and rigorous establishment and implementation of technical specifications that a tenderer may be encouraged, motivated and, most importantly, guided to submit an offer, and similarly, it is through the proper application of the same specifications that the Contracting Authority is to determine which offer merits to be chosen. So important are technical specifications that Contracting Authorities often resort to the use of International Standards in order to ascertain that the required qualities of a product are clearly met with. **The technical specifications laid down in the tender, thus, form the very foundation against which the evaluation criteria are established, leading to the award of the contract.**

Whereas in view of this, therefore, the rights of the Objector *qua* bidder have been severely prejudiced, since while the bid is to be evaluated against the published technical specifications, it transpires that the offer submitted by the Objector, despite being absolutely compliant with the technical specifications, is being rejected solely and exclusively on subjective criteria which do not form part of the technical specifications. Thus, the compliance with the technical specifications is being ignored and set aside, only to be substituted by the Evaluation Committee's subjective and irrelevant observations which never formed part of the basis on which the offers were to be made and adjudicated.

Whereas the subjective nature of the considerations made in the refusal go diametrically against the objective criteria set out in the tender dossier and which are the basis on which the tender ought to have been determined and adjudicated.

Whereas in view of the above reasons, such decision is clearly unfounded, and the Objector is of the opinion that it should be quashed.

3. *About the fact that the introduction of adjudication criteria which were not included in the technical specifications renders the process arbitrary*

Whereas so important are technical specifications that Regulation 53(6) of the Public Procurement Regulations (S.L. 174.04) states that

> *Technical specifications shall afford equal access of economic operators to the procurement procedure and shall not have the effect of creating unjustified obstacles to the opening up of public procurement to competition.*

Whereas since technical specifications must have these qualities, it also follows that a tender shall not include criteria which are used for the evaluation of the bids put forward without these having formed part of the said specifications. However, this is specifically what has happened in the present case.

Whereas **if such criteria on which the selection is based are not laid down, then the entire procurement process is put at jeopardy** as there is no guidance for the Evaluation Committee to go by and likewise, there is no basis upon which the criteria ensuring equal treatment and fairness can be applied, specifically as happened in this particular case. Such lack of clarity, while objectionable in its own right, also renders the entire process arbitrary and thus, totally against the most important principles of clarity, transparency and impartiality which form the very backbone of the public procurement process. In fact, as expounded above, **the way in which the Evaluation Committee acted in the present scenario was such as to constitute a material change** from that which was required in terms of the technical specifications. The technical specifications laid down in this case merely required the devices to be 'ready for use' and no other requirement was made.

Whereas the award criteria shall not be such as to create an unrestricted freedom of choice on the part of the Contracting Authority[5]. Above, it was also indicated that in terms of law, the selection criteria are to be based on the technical specifications. Consequently, it follows, that if the Contracting Authority, in the present case, **rejected and considered as not up to specifications the Objector's bid because it did not appear to meet criteria which *did not* form part of the technical specifications, such rejection is absolutely *ultra vires*** and a direct breach of the most basic of the principles of natural justice. This view is supported by the *Manual of Procedures*[6] which lays down in no unclear terms that *"Award criteria shall not have the effect of conferring an unrestricted freedom of choice on the Contracting Authority."*[7]

Whereas the selection criteria are those listed in the technical specifications. Consequently, in view of Regulation 187(1) of the Public Procurement Regulations, it cannot be said that the Objector did not meet the 'selection criteria' on the basis of 'requirements' which were never laid down in the technical specifications. Thus, to use the very words of the law, the Objector's *"tender shall be considered admissible"*. In other words, the Objector's offer was totally and completely in line with the technical specifications, consequently, it was totally compliant with what the Contracting Authority set out to acquire. The supply offered by the Objector was totally in line with the specifications and fully functional; there was absolutely no ground on which it could be rejected.

Whereas Regulation 53(1) of the Public Procurement Regulations states that the technical specifications shall be laid out in the tender's documents and that they are to lay down the requirements of the Contracting Authority. No requirement was made for any element as subjective as the Evaluation Committee deemed fit to introduce through its interpretation.

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[5] In Article 67(4) of Directive 2014/24/EU and Regulation 239 of S.L. 174.04 it us stated that: *"Award criteria shall not have the effect of conferring an unrestricted freedom of choice on the contracting authority. They shall ensure the possibility of effective competition ..."*

[6] Manual of Procedures, Public Procurement Regulations, 2016 (SL 174.04), Policy Development and Programme Implementation Directorate, Version 1.1 – Department of Contracts, Ministry for Finance.

[7] Ibid, Page 139.

Whereas effectively the manner in which the Evaluation Committee decided was such as to constitute a modification of the award criteria after the offers submitted were opened. This manifestly runs against the very spirit of public procurement procedures, and runs directly against the *Guidelines for Tender Evaluation Committees (TEC)*[8] which state that *"The Evaluation Committee* ***shall refer to the tender specifications included in the tender*** *under review so as to ensure that the documents and details required have been included in the forms and documents submitted by each tenderer"*[9] (emphasis added).

Whereas importantly in this case, as distinction has to be made; there is a material difference between requiring controls to be 'ready to use' and requiring controls to be 'supplied in liquid form, requiring no preparation whatsoever.' These are two different scenarios and the latter is not what the tender document required. Thus the Evaluation Committee was erroneous in asserting that the device offered by the Objectors was not to be deemed ready to use. The Contracting Authority should not necessarily be entitled to treat those two requirements as interchangeable.

Whereas in this context reference is to be made to a decision of this Board[10] wherein it was stated as follows:

> *Again, this Board highlights the importance to Contracting Authorities about the need to be very much clear in the drafting of tender documents.* ***A Contracting Authority cannot request certain characteristics / specifications in a tender document and then evaluate the bids using a different 'ruler'.*** (emphasis added)

Whereas this was also confirmed in another decision of the Board where it was made clear that the *"This Board has always provided guidance that the tender in question should be evaluated under its*

[8] Standard Operating Procedures (SoP); Guidelines for Tender Evaluation Committees (TEC), Version 1.1, Department of Contracts (April 2019).
[9] Ibid, Point 3.2.
[10] Case 1777 – SPD3/2022/012, 16th August 2022.

own merits,"[11] and that therefore, technical offers must be assessed against the specifications actually published, rather than against additional criteria introduced during the evaluation.

Whereas this is exactly what the Evaluation Committee did in this case, where it adopted a more restrictive interpretation than was reasonably transparent from the tender documentation.

Whereas in view of the above reasons, such decision is clearly unfounded, and the Objector is of the opinion that it should be quashed.

4. *About the fact that the technical parameters of the tender had been fundamentally altered*

Whereas as can be determined from the above, the way in which the Contracting Authority acted was such as to alter the technical parameters of the lot in question, and this after the offers were submitted.

5. *About the fact that the Evaluation Committee should have sought clarification*

Whereas in the present case, the Evaluation Committee reached its own conclusions using factors falling outside the scope of the present tender, and did not use the mechanism afforded by the clarification procedure. The Evaluation Committee should not automatically resort to rejection where a technical requirement admits of a reasonable interpretation requiring further examination.

Whereas this was confirmed in the another decision of this Board[12] where it was held as follows:

> *Every effort, without breaching any of the roles of the Public Procurement Regulations, should be made to save an advantageous Tender. In this*

[11] Case 1618 – CFT 020-0058/21 CPSU 3878/20, 20th August 2021.
[12] Case 1222 – CFT 020-0459/18, 18th October 2018.

particular case, an ambiguity had arisen and the Evaluation Committee should have sought clarifications on this issue, which was the sole reason for Krypton Chemists Limited's offer rejection, at that stage of the tendering procedure. In doing so, the Evaluation Committee would have applied the principle of proportionality and at the same instance, the latter would not have rejected a Tender without exercising its power to seek clarification.

3. Proportionality

It is a general principle of the European Union Law, that member states are bound by the Principle of Proportionality. Moreover, the Procurement Directive specifically calls for the award of contracts in member states to comply with this principle.

In this particular case, the main objective of the Contracting Authority was that it procures the product at the most advantageous price, (after satisfying the Administrative and Technical compliancy tests.) The Evaluation Committee had to assess whether a clarification will constitute a "recognised means" of pursuing the identified objective and in this case, a clarification would have revealed that such an issue was due to a careless clerical error in the Product Code Number. At the same instance, through such a clarification, the Evaluation Committee would have also confirmed that, the correct code number was also included in the Appellants' financial offer.

One of the basic requisites of the Principle of Proportionality is that the Contracting Authority should not adopt excessive measures and in this particular case, this Board opines that the Evaluation Committee opted to disqualify the Appellants' Bid due to an error in a products' code number while the same product was denoted by the latter with the correct specifications.

This Board would respectfully refer to a very important judgement, namely R (Hoole & Co) vs Legal Services Commission – UK which amplifies the duty of the

Evaluation Committee to seek clarifications and under what circumstances, as follows:

"In my judgement, the critical factor which gives rise, or may give rise, to a duty to seek clarification is where the tender as it stands cannot be properly considered because it is ambiguous or incomplete or contains an obvious clerical error rendering suspect that part of the bid. If the inability to proceed with a bid, which may be an advantageous addition to the competitive process, can be resolved easily and quickly it should be done, assuming there is no change to the bid or risk of that happening. If there is an obvious error or ambiguity or gap, clarifying it does not change the bid because, objectively the bid never positively said otherwise"

This Board is not, in any way, suppressing the principle of selflimitation which the Evaluation Committee has to adhere to, but rather to emphasize that, in specific cases such as this particular evaluation process, the application of the Principle of Proportionality will not alter or give an advantage to the particular Bidder but will allow the Contracting Authority to achieve its objectives in an even and equitable manner. (added emphasis)

Whereas what is more, in the present case, it was specifically declared by the Objectors that the devices were indeed ready for use. Such declaration, forming part of the documentation specifically required by the tender itself, should be given its due weight and should be duly considered. Consequently, rather than this being disregarded as happened in this case, the principle of proportionality should have been applied and such document should have been duly considered and given its due weight. The Evaluation Committee, thus, should have examined the complete technical information before concluding that the device was non compliant, and also sought use of the mechanism of clarification. This was confirmed in a decision of this Board as follows[13]:

[13] Case 2091 – CT2007/2021, 2nd April 2025.

Indeed, members of the second evaluation committee admitted under oath that they did not take the self-declaration into account. The Board also refers to the Court of Appeal's decision dated 30 July 2018 in the case of ***Bonnici Bros Projects Ltd et v. Ministru Ghas-sahha et*** *and the decision of the 25th June 2018 in the names of* ***Rockcut Limited v. Id-Direttur Generali tad-Dipartiment tal-Kuntratti et*** *where the Court of Appeal held that:*

"l-offerent m'ghandux jigi skwalifikat fuq in-nuqqas tal-ghotja ta xi taghrif mitlub fid-dokument tassejha, jekk kemm il-darba l-kumitat ta' evalwazjoni jkun jista jikseb dak it-tgharif min xi parti ohra tad-dokumenti li jigu sottomessi bhala parti minn dik l-offerta."

Furthermore, ***Public Procurement Note 40, Section 4 – Policy Content and Guidelines*** *stipulate:*

"In the eventuality that it transpires that ***the submitted information/documentation is*** *or appears to be ambiguous,* ***contrasting*** *[Board emphasis] or not sufficiently explicit and clear, Contracting Authorities/Entities, in their capacity as Evaluation Committees,* ***shall*** *[Board Emphasis] request the concerned Economic Operators to* ***clarify the necessary information/documentation*** *[Board Emphasis], within the appropriate Time Limit."*

In light of the above, the Board finds that the evaluation committee had before it a document ***(self-declaration – requested by the tender (pg. 29))*** *which clearly demonstrated compliance with the emissions requirement. Thus, it was incumbent upon the committee to seek clarification rather than dismiss the offer. The Board therefore disagrees with the evaluation committee's interpretation and procedure, and upholds the appellant's argument.*

6. *About incomplete technical assessment*

Whereas from the rejection letter, it can be understood that the Evaluation Committee has relied on the fact that the controls were lyophilized in rejecting the offer. However, the fact that a control requires reconstitution does not, by itself, establish that it is unsuitable for its intended purpose or that it cannot be used immediately following the prescribed preparation procedure.

Whereas the Evaluation Committee should have considered the actual device, including the preparation procedure, the time required for reconstitution, the stability of the reconstituted controls and whether any further preparation is necessary before use. As indicated, the device chosen in the tendering process requires much more human intervention in its use, yet, it was still deemed to be compliant. Thus, this is a clear case of the Evaluation Committee adopting a two weights, two measures approach, making its assessment inconsistent at best, and surely not in line with the principles of transparency, proportionality and good practice.

7. *About the declaration of conformity*

Whereas the rejection letter is contradictory. It states *"Bidder failed to submit the required Declaration of Conformity (NOTE 3) for item "912587 - Wash Solution A"* ***which is a CE-IVD marked product.***" (added emphasis). Thus, it takes it as a given that the device is a CE-IVD marked product, yet states that a Declaration of Conformity was not provided (Doc C, and the subsequent revision, Doc D).

Whereas this goes against the principle of proportionality in that while the same ground for refusal goes on to state *"Offer not technically compliant"*, (i) the Contracting Authority had already cognised that the device is a CE-IVD marked product yet (ii) it goes on to assert technical non-compliance, which is not the case.

Whereas this goes against the principle that decisions are to be clear which has already been addressed by this Board[14], stating *"This Board would again emphasise the importance of the responsibility put upon Contracting Authorities with regards to the drafting of the 'Rejection Letters' as*

[14] Case 1618 – CFT 020-0058/21 CPSU 3878/20, 20th August 2021.

these serve an important role in Public Procurement so that the participants in a tender procedure would have enough clear information as to whether they should appeal a case or not."

Whereas the rejection of the Appellant's offer on the basis that it failed to submit a Declaration of Conformity for item "912587 – Wash Solution A" is unjustified and overly formalistic.

Whereas the Appellant clearly identified the product being offered in its original Technical Offer by expressly indicating both its name, namely "Wash Solution A", and its exact product reference, namely "912587". There can therefore be no ambiguity whatsoever as to the identity of the product offered, nor is the Appellant seeking to introduce a different product or otherwise amend its offer following the closing date of the tender.

Whereas, furthermore, the Appellant had also submitted the product label and Instructions for Use (IFU) (Doc E and F), both of which clearly identified the product and evidenced its CE-IVD marking. Indeed, the Evaluation Committee itself expressly acknowledged in its letter of rejection that item 912587 is a "CE-IVD marked product", thereby confirming that the identity and regulatory marking of the product were already established through the documentation submitted with the original offer. This is thus taken as a given fact.

Whereas the Appellant had also submitted the relevant Declarations of Conformity in respect of the other components forming part of the NS-Prime solution, including the analyser, collection device, FIT reagent, calibrator and control, Calprotectin reagent, calibrator and control, and specimen diluent (Doc G). The only Declaration of Conformity which was inadvertently omitted was that relating specifically to the Wash Solution A.

Whereas, in these circumstances, the identity, nature, function and CE-IVD status of the product in question were already sufficiently identifiable and evidenced by the documentation submitted before the closing date. The outstanding Declaration of Conformity would merely have provided further formal confirmation of the regulatory status of the very same product, rather than introducing any new element into the Appellant's Technical Offer. Whereas in this regard, therefore, reference must be once more made to Case 1222 – CFT 020-0459/18, 18th October 2018 where it was stated as follows:

This Board would respectfully refer to a very important judgement, namely R (Hoole & Co) vs Legal Services Commission – UK which amplifies the duty of the Evaluation Committee to seek clarifications and under what circumstances, as follows:

"In my judgement, the critical factor which gives rise, or may give rise, to a duty to seek clarification is where the tender as it stands ***cannot be properly considered because it is ambiguous or incomplete or contains an obvious clerical error rendering suspect that part of the bid. If the inability to proceed with a bid, which may be an advantageous addition to the competitive process, can be resolved easily and quickly it should be done****, assuming there is no change to the bid or risk of that happening.* (added emphasis)

Whereas the submission of the said Declaration of Conformity would not have resulted in any alteration whatsoever to the Appellant's offer, would not have involved the substitution of the product offered, nor would it have improved or changed its technical specifications. It would simply have served to substantiate, by means of an additional supporting document, the regulatory conformity of the exact product which had already been expressly identified and offered by the Appellant.

Whereas this distinction is particularly relevant in determining whether the omission could properly be treated as non-rectifiable. The Appellant is not seeking to remedy a deficiency in the product itself or to replace an inadequately identified product with a different one, but is merely seeking to provide documentary confirmation concerning a product whose identity and CE-IVD marking were already apparent from the original submission.

Whereas, furthermore, the approach adopted by the Evaluation Committee appears inconsistent with the rectification already permitted during the evaluation of the Appellant's offer in respect of item "915335", whereby the Appellant was allowed to submit supporting documentation to substantiate a product which had already been clearly identified in its original Technical Offer. The same principle ought to have been applied in the present instance, particularly since the

submission of the missing Declaration of Conformity would likewise have served only to substantiate an already identified product, without altering the substance of the offer or conferring any competitive advantage upon the Appellant.

Whereas, consequently, the Appellant submits that the omission in question ought not to have resulted in the outright rejection of its offer as technically non-compliant, and that the Evaluation Committee ought to have permitted the submission of the outstanding Declaration of Conformity as a clarification or supplementary supporting document, particularly in light of the documentation already submitted and the rectification permitted in respect of item 915335.

8. About the obligation to exercise discretion in a just and proper manner

Whereas furthermore, the principles of natural justice dictate that if there is a discretion that is to be exercised, this must be exercised in an informed and just manner in order to lead to an equitable, just, logical and predictable outcome. Justice must not only be done, but it must also be seen to be done, and the circumstances of the present case do not give much comfort to such a principle which is at the very basis of the rule of law. The existence of discretion brings along the duty to actually (i) exercise such discretion and (ii) to exercise it in a just and informed manner. In this case, the appellant humbly submits that the discretion was not exercised in an equitable manner as there is a clear inconsistency in the way in which the Evaluation Committee decided in relation to different criteria on the Technical Specifications sheet. Furthermore, the Evaluation Committee's election to introduce further conditions only at the adjudication stage is **ultra vires**.

Whereas it cannot be argued that discretion was properly exercised, since as shown above, the reasons given for the rejection of the offer is one which is manifestly inconsistent with the way in which the Evaluation Committee decided in relation with other elements of the same Technical Specifications sheet. In view of this, it follows, thus, that the discretion that was

exercised was not exercised properly, since the result is not intelligible and is not one which can be traced back logically to the facts upon which it was supposed to have been based.

Whereas therefore, the Objector is of the humble opinion that the decision in question should be quashed.

9. *About the fact that the Contracting Authority did not act according to procedure*

Whereas moreover the Objector humbly submits that in the event that the above grievances / submissions are not upheld, the Honourable Board should also consider whether the Contracting Authority and / or the Evaluation Committee acted according to the rules and regulations governing this particular procedure.

In view of the above, the Objector is hereby humbly requesting:

1. That the decision dated 13th November 2026, whereby it was decided that the offer made by the Objector was found to be technically non-compliant be annulled, quashed, revoked and cancelled; and

2. That the offer submitted by the Objector with respect to the call for offers in question is accepted; and

3. That subordinately, in the event that the above requests are not acceded to, that the whole process be declared null and void.

Av. Robert Galea
91B, Mile End Street, Hamrun
galealegal@gmail.com

Doc A

DIPARTIMENT TAL-KUNTRATTI
Notre Dame Ravelin
Floriana FRN 1601 – MALTA

DEPARTMENT OF CONTRACTS
Notre Dame Ravelin
Floriana FRN 1601 – MALTA

Contact Number: +356 2378 1001
e-Mail: info.contracts@gov.mt
website: www.contracts.gov.mt

13th November 2026

ProCare Ltd.
TID 245163

REFERENCE: CT2058/2026

SUBJECT: FRAMEWORK CONTRACT FOR THE SUPPLY OF IFOBT AND CALPROTECTIN TESTING ON A PAY-PER-USE BASIS

Dear Sir/Madam,

Thank you for participating in the above-mentioned tender procedure. However, I regret to inform you that the offer submitted by your company was found to be technically non-compliant as follows:

"As per Section 3, Specifications, Clause 2.5, "All internal controls (minimum of two levels) and calibrators required for the duration of the contract period must be ready to use and are to be provided in sufficient quantities free of charge." The Bidder submitted Technical Documentation (Note 3), specifically the Instructions for Use (IFU) for the controls, titled "910873_FIT NS-Prime Control_IFU_Rev.2_20260701_DRAFT." The IFU states that the controls are lyophilized and therefore require preparation prior to use. Consequently, the controls cannot be considered "ready to use" as required under Clause 2.5.

Bidder failed to submit the required Declaration of Conformity (NOTE 3) for item "912587 - Wash Solution A" which is a CE-IVD marked product. A valid Declaration of Conformity for the product being offered must be provided as per Technical Offer under Section II (6.) and Clause 2.12 of Section 3 of the Technical Specifications. This requirement applies to items subject to the In Vitro Diagnostic Medical Devices Regulation (IVDR; Regulation (EU) 2017/746) and, during the applicable transition periods, the In Vitro Diagnostic Medical Devices Directive (IVDD; Directive 98/79/EC). As this requirement is classified as NOTE 3, it is non-rectifiable. Offer not technically compliant."

The tender was recommended for award to **TID 245143 Scientech Ltd for the amount of €624,000.00 excluding VAT**, this being the cheapest priced tender satisfying the administrative and technical criteria.

DIPARTIMENT TAL-KUNTRATTI
Notre Dame Ravelin
Floriana FRN 1601 – MALTA

DEPARTMENT OF CONTRACTS
Notre Dame Ravelin
Floriana FRN 1601 – MALTA
Contact Number: +356 2378 1001
e-Mail: info.contracts@gov.mt
website: www.contracts.gov.mt

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 Monday 23rd November 2026 against a deposit of €5,250.00.**

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,

Joseph Anthony Zammit

f/ Director General (Contracts)

REFERENCE NUMBER: CT2398/2021

SUPPLIES TENDER FOR THE SUPPLY OF ENZYME IMMUNOASSAY - CHEMILUMINESCENT KITS WITH EQUIPMENT ON LOAN

www.etenders.gov.mt

This project is being financed through local budget funds.

Department of Contracts
Notre Dame Ravelin, Floriana FRN 1600, Malta.
Tel: (356) 21220212. Fax: (356) 21247681
Email: info.contracts@gov.mt

Special Specifications:

1. All kits must come from same source. Kits and equipment must be CE marked and supplied with a certificate of Analysis and MSDS with each delivery. All items supplied throughout the contract period must be compliant with the respective EU's in vitro diagnostic regulations (IVDR) that are in force from time to time.

2. All test kits must be adapted to run on TWO NEW FULLY AUTOMATED RANDOM ACCESS Analyser with a minimum throughput of 180 tests per hour and stat processing.

3. The Analysers must include stand-alone laser printers on loan (all consumables to be included).

4. The Analysers supplied must be equipped with automated and manual barcode reading of samples and automated barcode reading of reagents.

5. The Analysers supplied must be equipped with clot/air bubble detection.

6. The Analysers supplied must be equipped with the facility of storing a minimum of 25 kits on board.

7. The Analysers supplied must be equipped with a UPS which will keep it running in case of power failure for 15 minutes.

8. Quality water: If the supplied analysers require the use of high quality water, a water purification system must be provided ON LOAN to supply water up to the level of quality (including bacterial decontamination) recommended by the manufacturer. The water supply unit/s, all consumables required for its operation and maintenance must be included in the offer for the whole duration of the contract period.

9. The Analysers required to perform these tests are to be supplied on loan basis for the duration of the contract/or until kits procured from this tender are in use.

10. In the eventuality that both Analysers break down, the down time cannot exceed 24hrs. If the downtime exceeds 24hrs the tenderer will have to outsource the pending tests at his own expense.

11. The analysers must have backup facilities and QC data analysis and review software.

12. Preventive Maintenance (periodic or otherwise as dictated by the analysers supplied) is to be performed and documented by the tenderer's technical staff. Written reports must be prepared and handed to the laboratory following any work carried out on the analysers.

13. No parking arrangements shall be made at Mater Dei Hospital by the Client for the Contractor's employees to attend to the laboratories for Preventive and/or Corrective Service and Maintenance.
14. Any other test that might be introduced during the duration of this cycle would need to be provided at the same Tender conditions.

15. Tender offer must include proportionate quantities (as dictated by the kit protocol supplied) of all accessory reagents, consumables, controls and calibrators (Ready to use).

16. Tender offer must include user training for the Analysers supplied for two scientists either locally or at the supplier's facility abroad.

17. Certificate of Agreement for Interface:

    The analyser must include the capability to interface with the Laboratory Information System (LIS) to exchange analysis data and maintain patient files. The current LIS in use at the laboratories is 'iLAB' by Dedalus Group, formerly DXC. The bidder must be able to work with by Dedalus Group so that a fully functional interface between both systems is installed during commissioning (or on a date agreed with Mater Dei Hospital) of the analyser(s). A completed

Doc C

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku,
Osaka 540-8575, Japan

Addendum to the original Declaration of Conformity

As of October 1, 2023, the Person Responsible for Regulatory Compliance has been changed.

PREDECESSOR
Hirohiko Sakomoto, Ph.D.

SUCCESSOR
Tetsuya Kosaka, Ph.D.

COMPANY REPRESENTATIVE: Tetsuya Kosaka, Ph.D.

TITLE: Person Responsible for Regulatory Compliance

COMPANY: Alfresa Pharma Corporation

PLACE: Osaka, Japan

SIGNATURE:

DATE: December 4, 2023

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Wash Solution A	912587	4987274W0580WSA00G9
Intended Purpose	**Photo**	
Wash Solution A is intended to be used for cleaning a reaction cuvette, sampling probe, reagent probes, and mixing bar of a Discrete Clinical Chemistry Analyzer NS-Prime or AA01.	N/A	

Device Classification		**Common Specifications**
Class	A	N/A : These products are classified into the category of <Class A>
Rule	IMPLEMENTIN RULES, 1.3. Rule 5	

The [Manufacturer] declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
- Classification, labelling and packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006
- On packaging and packaging waste Directive 94/62/EC

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

COMPANY REPRESENTATIVE: Hirohiko Sakamoto Ph.D.

TITLE: Quality Assurance Manager **SIGNATURE:** H Sakamoto

PLACE: Osaka, Japan **DATE:** 27/07/2023

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Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, JAPAN

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Wash Solution A	912587	4987274W0580WSA00G9
Intended Purpose	**Photo**	
Wash Solution A is intended to be used for cleaning a reaction cuvette, sampling probe, reagent probes, and mixing bar of a Discrete Clinical Chemistry Analyzer NS-Prime or AA01.		

IVDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	A	N/A : This product is classified into the category of < Class A>
Rule	IMPLEMENTING RULES, 1. 3. Rule 5	

Alfresa Pharma Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
- Classification, labelling and packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006

COMPANY REPRESENTATIVE: Hirohiko Sakamoto, Ph.D.

TITLE: General Manager, Quality Assurance **SIGNATURE:** H Sakamoto

PLACE: Osaka, Japan **DATE:** 20/04/2022

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of Alfresa Pharma Corporation.

MANUFACTURER		
Name of Company SRN	**Address**	**Person Responsible for Regulatory Compliance (PRRC)**
Alfresa Pharma Corporation JP-MF-000008778	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	Hirohiko Sakamoto, Ph.D General Manager Quality Assurance

UDI SYSTEM	
Product Name	**Basic UDI-DI**
Wash Solution A	4987274W0580WSA00G9

PRODUCT IDENTIFICATION		
Product Name	**Model/REF**	**Identification and Traceability**
Wash Solution A	912587	4987274W0580WSA00G9
Intended Use		
Wash Solution A is intended to be used for cleaning a reaction cuvette, sampling probe, reagent probes, and mixing bar of a Discrete Clinical Chemistry Analyzer NS-Prime or AA01.		

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Applied**
Class A	According to Article 48(10), Regulation (EU) 2017/746 ・Assessment of the technical documentation	Regulation (EU) 2017/746

Reference to any CS used	
Reference	**Tittle**
N/A	These products are classified into the category of < Class A>

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

REGISTRATION INFORMATION		
Notified Body and ID #	**Conformity assessment procedure performed**	**EC certificate number**
N/A (ClassA)		

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax emergoeurope@ul.com

We hereby declare that the IVD medical device(s) specified above meet the provision of the Regulation (EU) 2017/746 for IVD medical devices.

NAME OF PRRC: Hirohiko Sakamoto, Ph.D.

TITTLE: General Manager, Quality Assurance

SIGNATURE: H Sakamoto

PLACE & DATE (DD/MM/YY) : Osaka, Japan, 08/04/2022

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**SRN**
Emergo Europe B.V.	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	NL-AR-000000116

PRODUCT IDENTIFICATION		
Product Name	**Product Code**	**Basic UDI-DI**
Wash Solution A	912587	4987274W0580WSA00G9
Intended Purpose		
Wash Solution A is used for cleaning reaction cuvettes, sampling probes, reagent probes, and mixing bars of Discrete Clinical Chemistry Analyzers NS-Prime and AA01.		

IVDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	A	N/A – No Common Specifications applicable
Rule	Regulation (EU)2017/746, ANNEX VIII, 1.3 and 2.5 Rule 5 (a)	

The Alfresa Pharma Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
- Classification, Labelling and Packaging of substances and mixtures (CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006

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REVISION HISTORY:		
Version	**Date of Issue/Revision**	**Revision**
1.0	April 8, 2022	First Edition
2.0	April 20, 2022	Change of form Addition of European Representative's SRN Addition of CLP and REACH to the regulatory section
3.0	July 27, 2023	Change of European Representative's address Addition of PPWD to the regulatory section
4.0	December 4, 2023	Change of PRRC
5.0	August 21, 2026	Addition of revision history, including a revision number in the header PPWD has been removed from the regulatory section, as a new Declaration of Conformity for the PPWR has been issued

COMPANY REPRESENTATIVE: Tetsuya Kosaka, Ph.D.

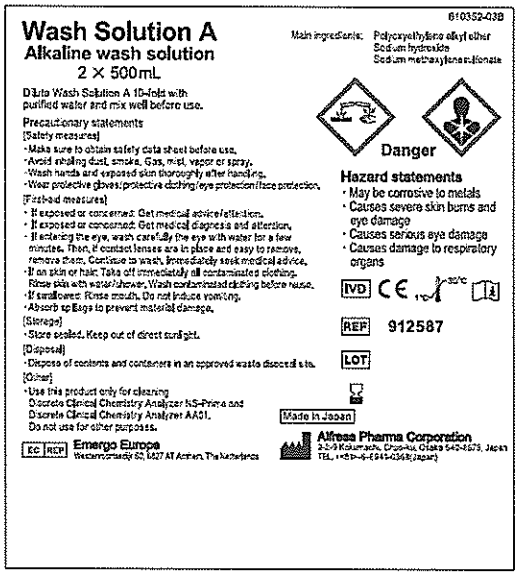
TITLE: Person Responsible for Regulatory Compliance **SIGNATURE:**

PLACE: Osaka, Japan **DATE:** August 21, 2026

912587
Wash Solution A
Package (Product bag)

Doc E

Package label



610352-03B

Wash Solution A
Alkaline wash solution
2 × 500mL

Main ingredients: Polyoxyethylene alkyl ether
Sodium hydroxide
Sodium methallylenesulfonate

Dilute Wash Solution A 10-fold with purified water and mix well before use.

Precautionary statements
[Safety measures]
- Make sure to obtain safety data sheet before use.
- Avoid inhaling dust, smoke, Gas, mist, vapor or spray.
- Wash hands and exposed skin thoroughly after handling.
- Wear protective gloves/protective clothing/eye protection/face protection.

[First-aid measures]
- If exposed or concerned: Get medical advice/attention.
- If exposed or concerned: Get medical diagnosis and attention.
- If entering the eye, wash carefully the eye with water for a few minutes. Then, if contact lenses are in place and easy to remove, remove them. Continue to wash. Immediately seek medical advice.
- If on skin or hair: Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse.
- If swallowed: Rinse mouth. Do not induce vomiting.
- Absorb to Sags to prevent material damage.

[Storage]
- Store sealed. Keep out of direct sunlight.

[Disposal]
- Dispose of contents and contained in an approved waste disposal site.

[Other]
- Use this product only for cleaning Discrete Clinical Chemistry Analyzer bS-Prime and Discrete Clinical Chemistry Analyzer AA01. Do not use for other purposes.

EC REP Emergo Europe

Danger

Hazard statements
- May be corrosive to metals
- Causes severe skin burns and eye damage
- Causes serious eye damage
- Causes damage to respiratory organs

IVD REF 912587

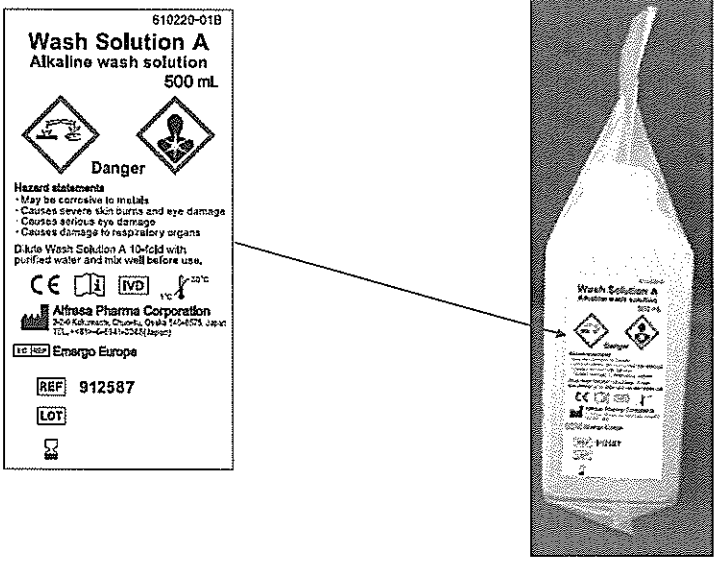
LOT

Made in Japan

Alfresa Pharma Corporation

912587
Wash Solution A
Bottle

Bottle label



610345-03E
* Date of revision
November 1,2023(Revision 4)

alfresa

Wash Solution A

Product list

Catalogue No.	Product name
912587	Wash Solution A

Manufactured by:

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan
For any incidents: incident-ivdr@alfresa-pharma.co.jp
For technical support: technical-support@alfresa-pharma.co.jp

Refer to the following URL for the package inserts in languages other than English:

https://alfresa-pharma-global.com/fit/products/

CE

FOR *IN VITRO* DIAGNOSTIC USE ONLY

1.0 INTENDED USE

Wash Solution A is used for cleaning reaction cuvette, sampling probe, reagent probes and mixing bar of the Discrete Clinical Chemistry Analyzers dedicated to our reagents only.

2.0 COMPONENTS

A pack of Wash Solution A includes two bottles of 500 mL stock solution (10X).
Wash Solution A contains:

Polyoxyethylene alkyl ether	5 %
Sodium hydroxide	3 %
Sodium metaxylene sulfonate	2 %

Safety Data Sheet is available upon request by users.
Hazard statements:



- May be corrosive to metals
- Causes severe skin burns and eye damage
- Causes serious eye damage
- Causes damage to respiratory organs

3.0 ADDITIONAL REQUIRED EQUIPMENT

3.1 Analyzer
Discrete Clinical Chemistry Analyzer NS-Prime
Discrete Clinical Chemistry Analyzer AA01
Note: Please contact us, if you want use with other analyzers dedicated to our reagents.

3.2 Others
Purified water (distilled or deionized (DI) water)
Graduated cylinder

4.0 REAGENT PREPARATION

Dilute Wash Solution A 10-fold with purified water and mix well before use. Do not use Wash Solution A as it is. Do not use at a dilution ratio other than 10-fold. Use diluted wash solution (1X) in analyzer's "Washing Bottle" within two years after dilution.
Caution: In handling it, wear rubber gloves and protective glasses.

5.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

5.1 Storage
Store at 1–30 °C. Use Wash Solution A within label expiry date. Keep out of direct sunlight.

5.2 Storage and shelf life after first opening
Tightly keep the lid on and store at 1–30 °C after opening Wash Solution A.

6.0 WARNINGS AND PRECAUTIONS

6.1 General precautions
For *in vitro* diagnostic use
Only experienced laboratory personnel should use this; the test using our reagents should be used in a manner consistent with Good Laboratory Practice. If you become aware of a serious incident related to this product, be sure to report it to the manufacturer and the competent authorities.

6.2 Safety precautions
1. Do not pipet by mouth.
2. Do not smoke, eat, or apply cosmetics in areas where patients' specimens or kit reagents are handled.
3. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
4. Take care to avoid self-inoculation, splashing to the mucous membrane, or generation of aerosols.
5. Wear laboratory gloves while handling patients' specimens or disposing of solid or liquid wastes.
6. Upon disposal of reagents or other materials, comply with relevant legal provisions.
7. All human specimens should be considered potentially infectious. Handle all specimens as if capable of transmitting HBV, HCV, HIV, or other microbes. Decontaminate and dispose of specimens and all potentially contaminated materials as if they contain infectious agents.
8. Wash Solution A is strongly alkaline. In handling it, wear rubber gloves and protective glasses. Upon exposure to the eye or skin, take emergency measures such as washing with plenty of water. Consult a doctor if necessary. Upon accidental ingestion, seek medical attention immediately.

6.3 Limitations
1. Do not use Wash Solution A bottles for purposes other than those stated.
2. Do not use Wash Solution A as it is, be sure to dilute 10-fold before using.
3. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.

7.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

Symbols	Meanings of the symbols
CE	CE marking
	Use-by date (Expiry date)
LOT	Batch code
REF	Catalogue number
	Manufacturer
EC REP	Authorized representative in the European Community (Authorized European representative)
IVD	*In vitro* diagnostic medical device (*In vitro* diagnostic)
	Temperature limit (for store)
	Consult instructions for use
	May be corrosive to metals Causes severe skin burns and eye damage Causes serious eye damage
	Causes damage to respiratory organs

* 8.0 INFORMATION ON PACKAGING MATERIALS

The following materials are used in the packaging of this product (accordance with Directive 94/62/EC on packaging and packaging waste).

Outer bag	
Outer bag HDPE 2	Outer bag label PAP 22

Product bottle		
Bottle HDPE 2	Cap PP 5	Bottle label PAP 22

Others
Instructions for use PAP 22

Otsuka
Otsuka Electronics Co., Ltd.

Declaration of Conformity

Manufacturer	**Otsuka Electronics Co., Ltd.**
Address	**3-26-3, Shodai-Tajika, Hirakata-shi, Osaka, 573-1132 JAPAN** **Tel: +81 72 855 8550 Fax: +81 72 855 8557**
SRN:	**JP-MF-000001943**
Manufacturing Site	**Otsuka Electronics Co., Ltd., Shiga Plant** **1-10, Sasagaoka, Minakuchi-cho, Koka-shi, Shiga, 528-0061 JAPAN**
European Representative	**Emergo Europe B.V.**
Address	**Westervoortsedijk 60, 6827 AT Arnhem, THE NETHERLANDS** **Tel: +31(0) 70 345 8570**
SRN:	**NL-AR-000000116**
Product Name:	**Discrete Clinical Chemistry Analyzer**
Model/Number:	**NS-Prime**
Classification:	**Class A, Rule: 5b (Annex Ⅷ of IVDR)**
Basic-UDI-DI:	**4987274W0201010101PRMN2**

Intended purpose:
"Discrete Clinical Chemistry Analyzer NS-Prime" (referred to as NS-Prime in this document) is an automated clinical chemistry analyzer that quantitatively measures and calculates the concentrations of hemoglobin, transferrin, and calprotectin in a sample from a calibration curve. It is equipped with all the units necessary for the reactions of various reagents and specimens from the collection to measurement stages, and uses the gold colloid colorimetric method to automatically calculates the change in absorbance at regular intervals generated by the reaction of human fecal samples with various reagents.

The NS-Prime uses a combination of reagents (FIT Hemoglobin NS-Prime, FIT Transferrin NS-Prime, and NESCAUTO Cp Auto NS-Prime), diluted solution (FIT NS-Prime specimen diluent), and cleaning solution (cleaning solution A), which are not included or provided with the NS-Prime.
The performance of the diagnostic reagents does not affect the measurement and performance functions of the instrument. It is an IVD (In vitro medical device) that provides the measurement results, and the performance of the diagnostic reagent itself affects the determination of the measurement results (hemoglobin, transferrin, and calprotectin concentrations).

We hereby declare that the above-mentioned product is in conformity with the provisions of the following EU Regulation, EC Directive and Standards. All the supporting documents relevant to this Declaration are maintained at the offices of the manufacturer.
Manufacturer is exclusively responsible to the declaration of conformity.

REGULATION and DIRECTIVE

General applicable regulation and directive:
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)
Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023

Otsuka

Otsuka Electronics Co., Ltd.

concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (Text with EEA relevance)

We confirm that the above-mentioned product meets the requirements of the following applicable Harmonized Standards (published in the Official Journal of the European Communities).
EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021,EN ISO 15223-1:2021

Place / Date Osaka Japan / 6. Oct, 2025

Signature Toshiyuki Mori

Name Toshiyuki Mori
Position Director, Quality Assurance Department

Issue Date of previous DoC: 2025/02/06

Otsuka
Otsuka Electronics Co., Ltd.

Declaration of Conformity

Manufacturer	**Otsuka Electronics Co., Ltd.**
Address	**3-26-3, Shodai-Tajika, Hirakata-shi, Osaka, 573-1132 JAPAN** **Tel: +81 72 855 8550 Fax: +81 72 855 8557**
SRN:	**JP-MF-000001943**
Manufacturing Site	**Otsuka Electronics Co., Ltd., Shiga Plant** **1-10, Sasagaoka, Minakuchi-cho, Koka-shi, Shiga, 528-0061 JAPAN**
European Representative	**Emergo Europe B.V.**
Address	**Westervoortsedijk 60, 6827 AT Arnhem, THE NETHERLANDS** **Tel: +31(0) 70 345 8570**
SRN:	**NL-AR-000000116**
Product Name:	**Discrete Clinical Chemistry Analyzer**
Model/Number:	**NS-Prime**
Classification:	**Class A, Rule: 5b (Annex Ⅷ of IVDR)**
Basic-UDI-DI:	**4987274W0201010101PRMN2**

Intended purpose:
"Discrete Clinical Chemistry Analyzer NS-Prime" (referred to as NS-Prime in this document) is an automated clinical chemistry analyzer that quantitatively measures and calculates the concentrations of hemoglobin, transferrin, and calprotectin in a sample from a calibration curve. It is equipped with all the units necessary for the reactions of various reagents and specimens from the collection to measurement stages, and uses the gold colloid colorimetric method to automatically calculates the change in absorbance at regular intervals generated by the reaction of human fecal samples with various reagents.

The NS-Prime uses a combination of reagents (FIT Hemoglobin NS-Prime, FIT Transferrin NS-Prime, and NESCAUTO Cp Auto NS-Prime), diluted solution (FIT NS-Prime specimen diluent), and cleaning solution (cleaning solution A), which are not included or provided with the NS-Prime.
The performance of the diagnostic reagents does not affect the measurement and performance functions of the instrument. It is an IVD (In vitro medical device) that provides the measurement results, and the performance of the diagnostic reagent itself affects the determination of the measurement results (hemoglobin, transferrin, and calprotectin concentrations).

We hereby declare that the above-mentioned product is in conformity with the provisions of the following EU Regulation, EC Directive and Standards. All the supporting documents relevant to this Declaration are maintained at the offices of the manufacturer.
Manufacturer is exclusively responsible to the declaration of conformity.

REGULATION and DIRECTIVE

General applicable regulation and directive:
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)
Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023

Otsuka

Otsuka Electronics Co., Ltd.

concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (Text with EEA relevance)

We confirm that the above-mentioned product meets the requirements of the following applicable Harmonized Standards (published in the Official Journal of the European Communities).
EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021,EN ISO 15223-1:2021

Place / Date Osaka Japan / 6. Oct, 2025

Signature Toshiyuki Mori

Name Toshiyuki Mori
Position Director, Quality Assurance Department

Issue Date of previous DoC: 2025/02/06

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku,
Osaka 540-8575, Japan

Addendum to the original Declaration of Conformity

As of October 1, 2023, the Person Responsible for Regulatory Compliance has been changed.

PREDECESSOR
Hirohiko Sakomoto, Ph.D.

SUCCESSOR
Tetsuya Kosaka, Ph.D.

COMPANY REPRESENTATIVE: Tetsuya Kosaka, Ph.D.

TITLE: Person Responsible for Regulatory Compliance

COMPANY: Alfresa Pharma Corporation

PLACE: Osaka, Japan

SIGNATURE: 

DATE: December 4, 2023

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
FIT NS-Prime Specimen Diluent	910874	4987274W01019001SPD016F
Intended Purpose	**Photo**	
FIT NS-Prime Specimen Diluent is a diluent for high concentration specimen. High concentration specimen to over the assay range has to be diluted with this diluent and be retested.	N/A	

Device Classification		**Common Specifications**
Class	A	N/A : These products are classified into the category of <Class A>
Rule	IMPLEMENTIN RULES, 1.3. Rule 5	

The [Manufacturer] declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
- Classification, labelling and packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006
- On packaging and packaging waste Directive 94/62/EC

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

COMPANY REPRESENTATIVE: Hirohiko Sakamoto Ph.D.

TITLE: Quality Assurance Manager **SIGNATURE:** H Sakamoto

PLACE: Osaka, Japan **DATE:** 27/07/2023

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Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, JAPAN

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
FIT NS-Prime Specimen Diluent	910874	4987274W01019001SPD016F
Intended Purpose	**Photo**	
FIT NS-Prime Specimen Diluent is a diluent for high concentration specimen. High concentration specimen to over the assay range has to be diluted with this diluent and be retested.		

IVDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	A	N/A : This product is classified into the category of < Class A>
Rule	IMPLEMENTING RULES, 1. 3. Rule 5	

Alfresa Pharma Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
- Classification, labelling and packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006

COMPANY REPRESENTATIVE: Hirohiko Sakamoto, Ph.D.

TITLE: General Manager, Quality Assurance **SIGNATURE:** H Sakamoto

PLACE: Osaka, Japan **DATE:** 20/04/2022

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of Alfresa Pharma Corporation.

MANUFACTURER		
Name of Company SRN	**Address**	**Person Responsible for Regulatory Compliance (PRRC)**
Alfresa Pharma Corporation JP-MF-000008778	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	Hirohiko Sakamoto, Ph.D General Manager Quality Assurance

UDI SYSTEM	
Product Name	**Basic UDI-DI**
FIT NS-Prime Specimen Diluent	4987274W01019001SPD016F

PRODUCT IDENTIFICATION		
Product Name	**Model/REF**	**Identification and Traceability**
FIT NS-Prime Specimen Diluent	910874	4987274W01019001SPD016F
Intended Use		
FIT NS-Prime Specimen Diluent is a diluent for high concentration specimen. High concentration specimen to over the assay range has to be diluted with this diluent and be retested.		

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Applied**
Class A	According to Article 48(10), Regulation (EU) 2017/746 ・Assessment of the technical documentation	Regulation (EU) 2017/746

Reference to any CS used	
Reference	**Tittle**
N/A	These products are classified into the category of < Class A>

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

REGISTRATION INFORMATION		
Notified Body and ID #	**Conformity assessment procedure performed**	**EC certificate number**
N/A (Class A)		

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax emergoeurope@ul.com

We hereby declare that the IVD medical device(s) specified above meet the provision of the Regulation (EU) 2017/746 for IVD medical devices.

NAME OF PRRC: Hirohiko Sakamoto, Ph.D.

TITTLE: General Manager, Quality Assurance

SIGNATURE: _____

PLACE & DATE (DD/MM/YY) : Osaka, Japan, 08/04/2022

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku,
Osaka 540-8575, Japan

Addendum to the original Declaration of Conformity

As of September 25, 2024, the new Specimen Collection Container A model has been added in the PRODUCT IDENTIFICATION as shown in the table below.

CURRENT PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Specimen Collection Container A	905860 910169 912173	4987274W05019001SCC007Z
Intended Purpose	**Photo**	
Specimen Collection Container A is a specimen container intended to be used by clinical laboratory technicians and subjects including patients to measure hemoglobin, transferrin, and calprotectin in feces, in combination with a Discrete Clinical Chemistry Analyzer NS-Prime or AA01.	N/A	

AMENDED PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Specimen Collection Container A	905860 910169 912173 914966	4987274W05019001SCC007Z
Intended Purpose	**Photo**	
Specimen Collection Container A is a specimen container intended to be used by clinical laboratory technicians and subjects including patients to measure hemoglobin, transferrin, and calprotectin in feces, in combination with a Discrete Clinical Chemistry Analyzer NS-Prime or AA01.	N/A	

COMPANY REPRESENTATIVE: Tetsuya Kosaka, Ph.D.

TITLE: Person Responsible for Regulatory Compliance

SIGNATURE:

DATE: 25/09/2024

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku,
Osaka 540-8575, Japan

Addendum to the original Declaration of Conformity

As of October 1, 2023, the Person Responsible for Regulatory Compliance has been changed.

PREDECESSOR
Hirohiko Sakomoto, Ph.D.

SUCCESSOR
Tetsuya Kosaka, Ph.D.

COMPANY REPRESENTATIVE: Tetsuya Kosaka, Ph.D.

TITLE: Person Responsible for Regulatory Compliance

COMPANY: Alfresa Pharma Corporation

PLACE: Osaka, Japan

SIGNATURE: 

DATE: December 4, 2023

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Specimen Collection Container A	905860 910169 912173	4987274W05019001SCC007Z

Intended Purpose	**Photo**
Specimen Collection Container A is a specimen container intended to be used by clinical laboratory technicians and subjects including patients to measure hemoglobin, transferrin, and calprotectin in feces, in combination with a Discrete Clinical Chemistry Analyzer NS-Prime or AA01.	N/A

Device Classification		**Common Specifications**
Class	A	N/A : These products are classified into the category of <Class A>
Rule	IMPLEMENTIN RULES, 1.3. Rule 5	

The [Manufacturer] declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
- Classification, labelling and packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006
- On packaging and packaging waste Directive 94/62/EC

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

COMPANY REPRESENTATIVE: Hirohiko Sakamoto Ph.D.

TITLE: Quality Assurance Manager **SIGNATURE:**

PLACE: Osaka, Japan **DATE:** 27/07/2023

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Specimen Collection Container A	905860 910169 912173	4987274W05019001SCC007Z
Intended Purpose	**Photo**	
Specimen Collection Container A is a specimen container intended to be used by clinical laboratory technicians and subjects including patients to measure hemoglobin, transferrin, and calprotectin in feces, in combination with a Discrete Clinical Chemistry Analyzer NS-Prime or AA01.	N/A	

Device Classification		**Common Specifications**
Class	A	N/A : These products are classified into the category of <Class A>
Rule	IMPLEMENTIN RULES, 1.3. Rule 5	

Alfresa Pharma Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
- Classification, labelling and packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006
- On packaging and packaging waste Directive 94/62/EC

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

COMPANY REPRESENTATIVE: Hirohiko Sakamoto Ph.D

TITLE: Quality Assurance Manager **SIGNATURE:** H Sakamoto

PLACE: Osaka, Japan **DATE:** 02. Nov. 2022

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Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, JAPAN

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Specimen Collection Container A	905860 910169 912173	4987274W05019001SCC007Z
Intended Purpose	**Photo**	
Specimen Collection Container A is a specimen container intended to be used by clinical laboratory technicians and subjects including patients to measure hemoglobin, transferrin, and calprotectin in feces, in combination with a Discrete Clinical Chemistry Analyzer NS-Prime or AA01		

IVDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	A	N/A : These products are classified into the category of < Class A>
Rule	IMPLEMENTING RULES, 1. 3. Rule 5	

Alfresa Pharma Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
- Classification, labelling and packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006

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Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, JAPAN

COMPANY REPRESENTATIVE: Hirohiko Sakamoto, Ph.D.

TITLE: General Manager, Quality Assurance **SIGNATURE:** H Sakamoto

PLACE: Osaka, Japan **DATE:** 25/04/2022

Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of Alfresa Pharma Corporation.

MANUFACTURER		
Name of Company SRN	**Address**	**Person Responsible for Regulatory Compliance (PRRC)**
Alfresa Pharma Corporation JP-MF-000008778	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	Hirohiko Sakamoto, Ph.D General Manager Quality Assurance

UDI SYSTEM	
Product Name	**Basic UDI-DI**
Specimen Collection Container A	4987274W05019001SCC007Z

PRODUCT IDENTIFICATION		
Product Name	**Model/REF**	**Identification and Traceability**
Specimen Collection Container A	905860 910169 912173	4987274W05019001SCC007Z
Intended Use		
Specimen Collection Container A is a specimen container intended to be used by clinical laboratory technicians and subjects including patients to measure hemoglobin, transferrin, and calprotectin in feces, in combination with a Discrete Clinical Chemistry Analyzer NS-Prime or AA01.		

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Applied**
Class A	According to Article 48(10), Regulation (EU) 2017/746 ・Assessment of the technical documentation	Regulation (EU) 2017/746

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Alfresa Pharma Corporation
2-2-9, Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Reference to any CS used	
Reference	**Tittle**
N/A	These products are classified into the category of < Class A>

REGISTRATION INFORMATION		
Notified Body and ID #	**Conformity assessment procedure performed**	**EC certificate number**
N/A (Class A)		

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax emergoeurope@ul.com

We hereby declare that the IVD medical device(s) specified above meet the provision of the Regulation (EU) 2017/746 for IVD medical devices.

NAME OF PRRC: Hirohiko Sakamoto, Ph.D.

TITTLE: General Manager, Quality Assurance

SIGNATURE: _____

PLACE & DATE (DD/MM/YY) : Osaka, Japan, 08/04/2022

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
FIT Hemoglobin NS-Prime	910869	4987274W0102039013HBR01Y9
FIT Hemoglobin NS-Prime Calibrator	910870	4987274W0102152205HBS00XK
FIT NS-Prime Control	910873	4987274W01021521HTC002H
FIT Hb/Tf Liquid Control	913938	4987274W01021521HTC012K

Intended Purpose	**Photo**
[FIT Hemoglobin NS-Prime] FIT Hemoglobin NS-Prime is a reagent to quantitatively determine human hemoglobin concentrations in feces using the Discrete Clinical Chemistry Analyzer NS-Prime, which employs a colloidal gold immune colorimetric and turbidimetric method. This reagent can be used for colorectal cancer screening in asymptomatic individuals. It can also be used for diagnostic aid of colorectal cancer in symptomatic individuals. [FIT Hemoglobin NS-Prime Calibrator] FIT Hemoglobin NS-Prime Calibrator is a calibrator to construct a calibration curve on Discrete Clinical Chemistry Analyzer NS-Prime and AA01. Specimen hemoglobin concentration is determined using the calibration curve. [FIT NS-Prime Control] FIT NS-Prime Control is a daily control for routine quality assurance. It should be run every day before specimen	N/A

assay to confirm that its value is within the acceptable range. [FIT Hb/Tf Liquid Control] FIT Hb/Tf Liquid Control is a daily control for routine quality assurance. It should be run every day before specimen assay to confirm that its value is within the acceptable range.	

IVDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	[FIT Hemoglobin NS-Prime]: C [FIT Hemoglobin NS-Prime Calibrator]: C [FIT NS-Prime Control]: C [FIT Hb/Tf Liquid Control]: C	N/A: There is no CS for these products.
Rule	Regulation (EU)2017/746, [FIT Hemoglobin NS-Prime]: ANNEX VIII, 1 and Rule 3 (h) of 2 [FIT Hemoglobin NS-Prime Calibrator]: ANNEX VIII, 1, 1.5 [FIT NS-Prime Control]: ANNEX VIII, 1, 1.6 [FIT Hb/Tf Liquid Control]: ANNEX VIII, 1, 1.6	

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
BSI Group The Netherlands B.V.	2797	IVDR Annex IX Chapter I and III	IVDR 744862

The Alfresa Pharma Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
- Classification, Labelling and Packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorization and Restriction of Chemical(REACH) Regulation (EC) No 1907/2006
- Packaging and packaging waste Directive 94/62/EC

COMPANY REPRESENTATIVE: Tetsuya Kosaka, Ph.D.

TITLE: Person Responsible for Regulatory Compliance **SIGNATURE:**

PLACE: Osaka, Japan **DATE:** December 3, 2025

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Alfresa Pharma Corporation	2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan	JP-MF-000008778

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
NESCAUTO Cp Auto NS-Prime	912681	4987274W0102019009CPR01ZP
NESCAUTO Cp Auto Calibrator	912684	4987274W0102152203CPS00Y4
NESCAUTO Cp Auto Control	912683	4987274W0102152003CPC00UE

Intended Purpose	**Photo**
[NESCAUTO Cp Auto NS-Prime] NESCAUTO Cp Auto NS-Prime is a reagent to quantitatively determine human calprotectin concentrations in feces using Discrete Clinical Chemistry Analyzer NS-Prime, which employs a colloidal gold immune colorimetric and turbidimetric method. Fecal calprotectin levels reflect the degree of inflammation in the intestinal mucosa and are known to correlate with histologic and endoscopic evaluations. This reagent is intended as an aid in the assessment of intestinal mucosal inflammation in inflammatory bowel disease (IBD) patients, and as an aid in the differentiation of IBD from irritable bowel syndrome (IBS). This reagent should only be used in adults and children with IBD or suspected of having IBD. For children, 5 years old or above. [NESCAUTO Cp Auto Calibrator] NESCAUTO Cp Auto Calibrator is a calibrator to construct a calibration curve on Discrete Clinical Chemistry Analyzer NS-Prime and AA01. Specimen calprotectin concentration is determined using the calibration curve.	N/A

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan

[NESCAUTO Cp Auto Control] NESCAUTO Cp Auto Control is a daily liquid control for routine quality assurance, which is used with Discrete Clinical Chemistry Analyzer NS-Prime and AA01. It should be run every day before specimen assay to confirm that its value is within the acceptable range.	

IVDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	[NESCAUTO Cp Auto NS-Prime]: B [NESCAUTO Cp Auto Calibrator]: B [NESCAUTO Cp Auto Control]: B	N/A: There is no CS for these products.
Rule	Regulation (EU) 2017/746, [NESCAUTO Cp Auto NS-Prime]: ANNEX VIII, 1 and Rule 6 of 2 [NESCAUTO Cp Auto Calibrator]: ANNEX VIII, 1, 1.5 [NESCAUTO Cp Auto Control]: ANNEX VIII, 1, 1.6	

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
BSI Group The Netherlands B.V.	2797	IVDR Annex IX Chapter I and III	IVDR 744862

The Alfresa Pharma Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
- Classification, Labelling and Packaging of substances and mixtures(CLP) Regulation (EC) No 1272/2008
- Registration, Evaluation, Authorization and Restriction of Chemical(REACH) Regulation (EC) No 1907/2006
- Packaging and packaging waste Directive 94/62/EC

COMPANY REPRESENTATIVE: Tetsuya Kosaka, Ph.D.

TITLE: Person Responsible for Regulatory Compliance **SIGNATURE:** Dkose

PLACE: Osaka, Japan **DATE:** December 3, 2025

BOV
Bank of Valletta

Bank of Valletta p.l.c
Registration Number: C 2833
Registered Office: 58 Zachary Street, Valletta VLT 1130 - Malta

Pay third party

Printed by: Mr. Pierre Calleja
Printed on: 23/11/2026 - 11.34
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Transaction details

Payer's name:	PROCARE LTD
Payee type:	Corporate Payee
Company name:	Cashier Malta Government
Relation:	Administrative Services
Reason:	Other
Payment details:	Deposit for Objection reference CT2058.2026
Currency:	EUR - Euro
Beneficiary IBAN/Account:	MT55MALT01100004000 1EURCMG5001H
Beneficiary IBAN/Account type:	Valid IBAN of country - Malta
Bank name:	Other bank
Bank address / Bank's BIC:	Let the bank apply the beneficiary bank BIC
Beneficiary address:	No
From account:	4002355137 6 (EUR)
Charges should be paid by:	Shared - I pay BOV charges; pays the beneficiary bank charges
Amount:	EUR 5,250.00
BOV to transfer the money:	as soon as possible
Receiving bank to get the money as:	normal priority payment
FPAD Result:	The name you entered is very similar to our records: CASHIER MALTA GOVERNMENT CALL ACCOUNT - GENERAL. If you continue without correcting it, the payment may be sent to the wrong person,and recovery may not be possible as it could result in fraud. This Verification of Payee check will not block the payment, but it is simply providing additional security. Please verify the payment details with the recipient before proceeding.
Saved template:	modify existing template

Additional information

Credit amount:	EUR 5,250.00
Debited amount (excluding charges):	EUR 5,250.00
Estimated amount to be withdrawn from account:	EUR 5,254.00
Transaction charge:	EUR 4.00

Transaction result

Status:	Your instructions have been processed successfully.
Transaction ID:	189105939