
**IN THE HIGH COURT OF JUSTICE** **Claim No:**

**BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES**

**COMMERCIAL COURT (KBD)**

**B E T W E E N :**

**THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE**

**Claimant**

**- and -**

**PPE MEDPRO LIMITED**

**Defendant**

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# PARTICULARS OF CLAIM

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## A. INTRODUCTION

1. By a contract dated 26 June 2020 (the "**Contract**"), the Defendant ("**PPE Medpro**") agreed to supply the Claimant ("**DHSC**") with 25 million sterile surgical gowns ("**Gowns**") for a total price of £122,000,000. The sum that DHSC in fact paid was £121,999,219.20 (the "**Price**"). As set out below, the Gowns supplied by PPE Medpro did not comply with the specification in the Contract, including the applicable regulatory regime. DHSC accordingly claims repayment of the Price, alternatively damages and/or an indemnity, and its costs of storing and disposing of the Gowns.

2. The Claimant is the Secretary of State for the Department of Health and Social Care. References to DHSC are references to the Claimant and his Department. So far as relevant to this claim, DHSC's responsibilities included at all material times the protection of the public's health through the health and social care system's response to Covid-19, which included procurement of essential medical supplies for the National Health Service ("**NHS**").

3. PPE Medpro is a company incorporated in England & Wales on 12 May 2020 under company number 12597000, with its registered address at 9 Dalton House, 60 Windsor Street, London, SW19 2RR. PPE Medpro supplied items commonly referred to as personal protective equipment ("**PPE**") to the NHS during the Covid-19 crisis. At all material times, PPE Medpro's directors were Anthony Page, Voirrey Coole and Maurice Stimler. Mr Page was, at all material times, PPE Medpro's sole shareholder, although DHSC's understanding is that PPE Medpro was backed by a consortium of business people.

## B. FACTUAL BACKGROUND TO THE CLAIM

4. By March 2020, the coronavirus disease 2019 ("**Covid-19**") was spreading throughout the UK. The Government needed to procure supplies that could be used by the NHS to enable staff to care for patients while protecting themselves and their patients against the risk of infection, as the disease was highly infectious.

5. A "PPE Cell" was established, which included an "Opportunities Team" which triaged opportunities and gathered information from potential suppliers, including documentary evidence that their manufacturers and the products to be supplied complied, or would comply, with the relevant technical requirements for PPE. The Opportunities Team passed that evidence to a technical assurance ("**TA**") team, which

reviewed the evidence in order for DHSC to decide whether to pursue an offer to supply PPE.

6. Owing to the circumstances of the Covid-19 pandemic, it was not possible for the TA team to inspect or test samples of PPE or to visit the PPE manufacturers with a view to ensuring technical compliance. Successful deals were closed by a "Closing Team". PPE Medpro made multiple offers to supply different types of PPE to DHSC and was therefore familiar with the relevant procurement process. DHSC also understood that PPE Medpro (or entities related to it) was involved in supplying other countries with PPE during the Covid-19 pandemic, including South Africa and Australia.

7. PPE Medpro initially approached DHSC on 13 May 2020 with an offer to supply 50 million *non-sterile* surgical gowns. DHSC pursued this offer until around 21 May 2020, when it determined that *non-sterile* surgical gowns were no longer needed. A revised proposal for 50 million *sterile* gowns was pursued from 2 June 2020 until around 16 June 2020, when all gown-related deals under negotiation were put on hold as the Government reviewed its requirements for such gowns. After some further negotiation, PPE Medpro ultimately made an offer to supply 25 million *sterile* gowns at £4.88 per gown, which was approved by DHSC. Accordingly, on 26 June 2020, the parties concluded the Contract for the supply of the Gowns for £122,000,000, subject to the terms set out in section C below.

## C. THE CONTRACT

8. The Contract is a written agreement consisting of a front page, order form, four schedules and a set of annexures marked "A1" to "A9". The following paragraphs set out the key provisions relevant to DHSC's claim. DHSC will rely on all relevant terms of the Contract for their full meaning and effect.

9. On the front page, the Contract recorded that PPE Medpro agreed to supply gowns to DHSC "*subject to the terms set out in the Order Form and schedules below*". PPE Medpro further agreed that it would "*supply to the Authority* [i.e. DHSC]*, and the Authority shall receive and pay for, the Goods on the terms of this Contract*". The front page also specified that "*the Contract consists of the terms set out in the Order Form and the Schedules, together with the annexes as stated.*"

10. The Order Form contains the following relevant provisions:

10.1. Section 5 provides that PPE Medpro shall provide the "*deliverable described below*" on the terms set out in the Order Form and the Schedules and Annex A and "*In the event of any conflict between this Order Form and the Schedules, this Order Form shall prevail.*"

10.2. Section 6 identifies the "*Deliverables*" that PPE Medpro had agreed to supply, namely 25 million sterile surgical gowns in various sizes. It also identifies the two Chinese factories that PPE Medpro was required to use to produce the Gowns. Section 6 also provides for delivery on an ex works basis.

10.3. Section 7 provides that "*The specification of the Deliverables is as set out in Annex A.1-A.9 [26.06.2020].*" A series of checkboxes confirm that the annexes contained documents including the "*Product tech spec*", "*Test Certification*" and "*EN Certification*".

10.4. Section 9 provides that the total price payable including VAT was £122,000,000.

11. Schedule 1 contains the following relevant provisions:

11.1. Clause 1 provides that:

> "*1.1 The standard Key Provisions at Clauses 1 to 2 of this Schedule 1 shall apply to this Contract.*
>
> *1.2 The optional Key Provisions at Clauses 3 to 12 of this Schedule 1 shall only apply to this Contract where they have been checked and information completed as applicable.*
>
> *1.3 Extra Key Provisions shall only apply to this Contract where such provisions are set out at the end of this Schedule 1.*"

11.2. Clause 2.1 provides an order of precedence in relation to the various parts of the Contract, as follows:

> "*2.1 Subject always to Clause 1.9 of Schedule 3 should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:*
>
> *2.1.1 Order Form*
>
> *2.1.2 Schedule 1: Key Provisions;*
>
> *2.1.3 Schedule 2: Terms and Conditions;*
>
> *2.1.4 Schedule 3: Definitions and Interpretations;*

*2.1.5 any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.*"

11.3. Clause 12, insofar as relevant, provided as follows:

"*12.2 The Supplier shall supply the PPE Goods to Authority in accordance with the terms of this Contract and in accordance with the relevant requirements of applicable laws and regulations applicable to the supply of PPE, including, as applicable, the EU PPE Regulation 2016/425, the Personal Protective Equipment (Enforcement) Regulations 2018 and the Medical Device Regulations 2002 (together the "PPE Laws").*

*12.3 Save in relation to any PPE Goods for which the Supplier has approval in accordance with the cross-Government Decision Making Committee and without prejudice to the generality of clause 12.2, the Supplier shall ensure for PPE Goods supplied:*

*12.3.1 the appropriate conformity assessment procedure(s) applicable to the PPE Goods have been followed;*

*12.3.2 all declarations of conformity and approvals required by PPE Laws are in place prior to the delivery of any PPE Goods to the Authority;*

*12.3.3 where required by PPE Laws, there is a CE mark affixed to the PPE Goods in accordance with the PPE Laws; and*

*12.3.4 where, necessary current EC-type examinations certificates are in place for the PPE Goods.* […]

*12.7 The Supplier shall ensure that each delivery of PPE Goods shall be properly labelled in accordance with PPE Laws and such labelling and any user instructions relating to the use of the PPE Goods is clearly legible and in English.*

*12.8 The Supplier shall ensure that all PPE Goods are covered by a valid EU Declaration of Conformity, translated into English and shall procure that this shall be retained by the Supplier and its Sub contractors for at least 10 years following the delivery date to the Authority.*"

12. Annex A1, so far as relevant to DHSC's claim, contained photographs of the packaging of the Gowns to be produced by Wujiang Tutaike Textile & Finishing Co Ltd (one of the two factories identified in the Contract), which showed that the Gowns would be: (i) double-wrapped, such that each Gown would be provided in an outer package, within which it would be wrapped in a piece of cloth; and (ii) the front of the outer packaging would peel away from the rest of the packaging in order for the package to be opened.

13. Schedule 2 contains the following relevant provisions:

13.1. Clause 1.1.5 provides that "*the Supplier* [i.e. PPE Medpro] *shall supply the Goods ordered by the Authority under this Contract* […] *in accordance with any quality assurance standards set out in the Key Provisions and/or in the Order Form*".

13.2. Clause 1.1.6 provides that "*the Supplier shall supply the Goods ordered by the Authority under this Contract* […] *in accordance with the Law and with Guidance*".

13.3. Clause 1.3 provides that

> "*Unless otherwise agreed by the Parties in writing, the Goods shall be new, consistent with any sample, and shall comply with any applicable specification set out in this Contract (to include, without limitation, the provisions of the Authority's requirements set out in the Order Form and the Supplier's response to such requirements) and any applicable manufacturers' specifications.*"

13.4. Clause 1.4 provides that: "*The Supplier shall ensure that all relevant consents, authorisations, licences and accreditations required to supply the Goods are in place prior to the delivery of any Goods to the Authority.*"

13.5. Clause 4, insofar as relevant to DHSC's claim, provides for DHSC to reject the Gowns in the following terms:

> "*4.2 Without prejudice to the provisions of Clause 4.6 of this Schedule 2 and subject to Clause 4.7 of this Schedule 2, the Authority shall visually inspect the Goods within a reasonable time following delivery (or such other period as may be set out in the Key Provisions, if any) and may by written notice reject any Goods found to be damaged, or delivered late, or otherwise not in accordance with the requirements of this Contract ("Rejected Goods"). The whole of any delivery may be rejected if a reasonable sample of the Goods taken indiscriminately from that delivery is found not to conform in all material respects to the requirements of the Contract.* […]
>
> *4.5 Where the Authority rejects any Goods in accordance with Clauses 4.2 and/or 4.6 of this Schedule 2 and the Authority no longer requires replacement Goods, the Authority may by written notice cancel its purchase obligations in relation to such quantity of Rejected Goods. Should the Authority have paid (in whole or in part) for such Rejected Goods the Supplier shall refund such payment along with any costs reasonably incurred by the Authority as a result of any such rejection to the Authority within*

*thirty (30) days of the Authority cancelling such purchase obligations and informing the Supplier that the Authority does not require replacements for such Rejected Goods.*

*4.6 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 4.7 of this Schedule 2, if at any time following the date of the delivery of any Goods, all or any part of such Goods are found to be defective or otherwise not in accordance with the requirements of this Contract ("Defective Goods"), the Supplier shall, at the Authority's discretion:* […]

*4.6.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 4.2 to 4.5 of this Schedule 2.* […]

*4.8 The Authority's rights and remedies under Clause 4.6 of this Schedule 2 shall cease within a reasonable period of time from the date on which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods or within such other period as may be set out in the Key Provisions, if any.*"

13.6. By clause 7, PPE Mepdro warranted and undertook the following matters (insofar as relevant to DHSC's claim):

"*7.1.1 the Goods shall be suitable for the purposes and/or treatments as referred to in the Order Form, be of satisfactory quality, fit for their intended purpose and shall comply with the standards and requirements set out in this Contract;* […]

*7.1.3 it shall ensure that prior to actual delivery to the Authority the Goods are manufactured, stored and/or distributed using reasonable skill and care and in accordance with Good Industry Practice;*

*7.1.4 without prejudice to the generality of the warranty at 7.1.3 of this Schedule 2, it shall ensure that, the Goods are manufactured, stored and/or distributed in accordance with good manufacturing practice and/or good warehousing practice and/or good distribution practice, as may be defined under any Law, Guidance and/or Good Industry Practice relevant to the Goods, and in accordance with any specific instructions of the manufacturer of the Goods;* […]

*7.1.16 where any act of the Supplier requires the notification to and/or approval by any regulatory or other competent body in accordance with any Law and Guidance, the Supplier shall comply fully with such notification and/or approval requirements;*

*7.1.17 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to supply*

*the Goods;* […]

*7.1.19 it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the supply of the Goods*".

13.7. Clause 7.2 contained further applicable warranties because, as explained in paragraph 16 below, the Gowns are medical devices. Clause 7.2, insofar as relevant to DHSC's claim, provides as follows:

> "*7.2 Where the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of the Goods under this Contract relates to medical devices and/or medicinal products (both as defined under any relevant Law and Guidance), the Supplier warrants and undertakes that it will comply with any such Law and Guidance relating to such activities in relation to such medical devices and/or medicinal products. In particular, but without limitation, the Supplier warrants that:*
>
> *7.2.1 at the point such Goods are supplied to the Authority, all such Goods which are medical devices shall have valid CE marking as required by Law and Guidance (or be subject to a Product Authorisation, as such term is defined in Schedule 4) and that all relevant marking, authorisation, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of such Goods shall have been complied with. Without limitation to the foregoing provisions of Clause 7.1 and 7.2 of this Schedule 2, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid CE marking, and evidence of any other authorisations, registrations, approvals or documentation required.*"

13.8. Clause 7.3 provided DHSC with the right to reject the Gowns in the event that cl. 7.2 was breached, in the following terms:

> "*If the Supplier is in breach of Clause 7.2 of this Schedule 2, then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Goods and the Supplier shall, subject to Clause 10.2 of this Schedule 2, indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach.*"

13.9. Clause 14 set out PPE Medpro's obligations in relation to packaging and labelling of the Gowns, insofar as relevant to DHSC's claim, in the following terms:

> "*14.1 The Supplier shall comply with all obligations imposed on it by Law relevant to the Goods in relation to packaging, identification, and obligations following end of use by the Authority.* […]
>
> *14.3 The Supplier shall comply with any labelling requirements in respect of the Goods: (a) specified in the Order Form; (b) agreed with the Authority in writing; and/or (c) required to comply with Law or Guidance and shall ensure that any labelling in respect of the Goods is in English.*
>
> *14.4 The Supplier shall ensure that all Goods that are required by Law or Guidance to bear any safety information, environmental information, any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality at the point such Goods are delivered shall comply with such requirements at the point of delivery.*"

13.10. Clause 28.5 excludes reliance on any representations, warranties or undertakings and provides for a waiver of any right to claim damages in the following terms:

> "*Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.*"

13.11. Clause 28.9 contains an entire agreement clause and provides for the Contract to be varied in signed writing by the parties' authorised representatives, in the following terms:

> "*This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the supply of the Goods to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Contract. Nothing in this Contract seeks to exclude either Party's liability for Fraud. Any tender conditions and/or disclaimers set out in the Authority's procurement documentation leading to the award of this Contract shall form part of this Contract.*"

14. Schedule 3 sets out the definitions and rules of interpretation applicable to the Contract. Insofar as relevant to DHSC's claim, it provides as follows:

14.1. Clause 1.1 contains the following definitions:

> "*Guidance*" is defined as "*any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health and Social Care, Monitor, NHS England, NHS Improvement, the Medicines and Healthcare Products Regulatory Agency, the Health & Safety Executive, the Office for Product Safety & Standards, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body*".
>
> "*Law*" is defined as "*any applicable legal requirements including, without limitation:*
>
> > *(a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales;*
> >
> > *(b) any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument);*
> >
> > *(c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972;*
> >
> > *(d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales;*
> >
> > *(e) requirements set by any regulatory body as applicable in England and Wales;*
> >
> > *(f) any relevant code of practice as applicable in England and Wales; and*
> >
> > *(g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above)*".

14.2. Clause 1.9 provides that:

> "*Where there is a conflict between the Supplier's responses to the*

*Authority's requirements (the Supplier's responses being set out in the order form) and any other part of this Contract, such other part of this Contract shall prevail.*"

15. Further, the Contract contains the following implied terms:

15.1. Pursuant to s. 13(1) of the Sale of Goods Act 1979 ("**SGA 1979**"), a term that the Gowns would correspond with their description.

15.2. Pursuant to s. 14(2) SGA, a term that the Gowns would be of satisfactory quality.

15.3. Pursuant to s. 14(3) SGA, a term that the Gowns would be reasonably fit for their purpose as sterile gowns to be used in the NHS.

## D. REGULATORY BACKGROUND TO THE CLAIM

16. The supply of medical protective equipment is subject to extensive regulation which, at the time, was governed by or derived from European legislation. In this case, the Gowns were provided as medical devices only and were therefore subject to the regime governing medical devices, but not PPE (as that term is defined in the relevant European legislation). The following paragraphs set out the key relevant provisions of the regulatory regime, without prejudice to DHSC's right to rely at trial on the full provisions of the legislation and guidance set out below for their full meaning and effect.

### D.1. The Market Surveillance Regulation

17. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (the "**Market Surveillance Regulation**") establishes an overall framework for, *inter alia*, the accreditation of products within the European Union.

18. Article 30 of the Market Surveillance Regulation establishes general principles of CE marking. Art. 1(20) defines "CE marking" as "*a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing*". In summary, Art. 30 provides, *inter alia*, as follows.

18.1. CE marking may only be affixed to products by the manufacturer or his authorised representative (Art. 30(1)).

18.2. CE marking may only be affixed where EU harmonisation legislation provides for CE marking (Art. 30(2)).

18.3. By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing (Art. 30(3)).

18.4. The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Community harmonisation legislation providing for its affixing (Art. 30(4)).

**D.2. The Medical Devices Regulations 2002 (SI 2002/618)**

19. The Medical Devices Regulations 2002 ("**MDR 2002**") implement Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (the "**Medical Devices Directive**"). Insofar as relevant to the claim, the MDR 2002 (as in force at the date of the Contract) provided as follows at the time of the Contract.

20. Reg. 2 set out the following relevant definitions:

20.1. The term "*CE marking*" means "*a conformity marking consisting of the initials "CE"*".

20.2. The term "*manufacturer*" means:

> "*(a) the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or*
>
> *(b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient*".

20.3. The term "*medical device*" means:

> "*any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or*

*therapeutic purposes or both and necessary for its proper application, which—*

*(a) is intended by the manufacturer to be used for human beings for the purpose of–*

*(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,* […]*; and*

*(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means* […]"

20.4. The term "*placing on the market*", in relation to a medical device, means:

"*the first making available in return for payment or free of charge of a new or fully refurbished device, other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market*".

20.5. The term "*supply*", in relation to a medical device, means:

"*(a) the supply of, or the offer or agreement to supply, the device; or*

*(b) the exposure or possession for supply of the device*".

21. Reg. 5 defined "*relevant device*" by reference to reg. 6, which determines the scope of Part II of the MDR 2002. Reg. 6 excludes types of device which are not relevant to this claim.

22. Reg. 7(1) provided for the classification of devices "*as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of* [the Medical Devices Directive]". Pursuant to Annex IX, Chapter III, paragraph 1.1, of the Medical Devices Directive, and subject to irrelevant exceptions, all non-invasive devices are in Class I.

23. Reg. 8 provided that:

"*(1) Subject to regulation 12, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it and the requirements set out in Regulation (EU) No 722/2012 (if applicable).*

*(2) Subject to regulation 12, no person shall supply a relevant device—*

*(a) if that supply is also a placing on the market or putting into service of that device; or*

*(b) in circumstances where that device has been placed on the market or put into service,*

*unless that device meets those essential requirements set out in Annex I which apply to it and the requirements set out in Regulation (EU) No 722/2012 (if applicable).*"

24. Annex I to the Medical Devices Directive contains, insofar as relevant, the following provisions:

> "*1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.* […]
>
> *3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer."* […]
>
> *5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.* […]
>
> *8.3 Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.*
>
> *8.4 Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.* […]
>
> *8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.* […]
>
> *13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.*
>
> *This information comprises the details on the label and the data in the instructions for use.*

*As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.*"

25. Reg. 10 provided for a requirement that medical devices bear a CE marking:

"*(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—*

*(a) meets the requirements set out in Annex XII;* […]*; and*

*(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.*

*(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—*

*(a) meets the requirements set out in Annex XII;* […]*; and*

*(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,*

*if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.*

*(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex XII, appears on—*

*(a) any sales packaging for that device; and*

*(b) the instructions for use for the device,*

*and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.*

*(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex XII, appears on—*

*(a) any sales packaging for that device; and*

*(b) the instructions for use for the device,*

*and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that*

*device.*"

26. Reg. 12(5) provided for derogations from Art. 10 in the following terms:

> "*Regulations 8 and 10 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.*"

27. Reg. 13(1) provided that CE markings could be applied only where certain conditions were fulfilled:

> "*A relevant device falling within Class I may bear a CE marking only if its manufacturer or his authorised representative—*
>
> *(a) fulfils the applicable obligations imposed by Annex VII;*
>
> *(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it; and*
>
> *(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.*"

28. Annex VII to the Medical Devices Directive provides for a declaration of conformity in respect of medical devices. In particular, paragraph 5 provides that manufacturers placing products on the market in a sterile condition must comply with a procedure in one of Annexes II, IV, V or VI as regards the securing and maintaining of sterility. Annexes II, IV, V and VI set out procedures for ensuring a product's conformity to the requirements of the Medical Devices Directive generally, in particular in: Annex II, sections 3, 4 and 5; Annex IV, section 4; Annex V, sections 3 and 4; and Annex VI, sections 1, 3 and 4.

### D.3. The Commission Recommendation

29. Commission Recommendation EU 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat (the "**Commission Recommendation**") was issued in order to ensure the availability of PPE and medical devices throughout the European Union and to invite economic operators to deploy all measures at their disposal to ensure that the supply of PPE and medical devices would match the increasing demand (Art. 1). The Commission Recommendation was "*Guidance*" within the meaning of the Contract,

and therefore formed part of the Contract.

30. Paragraph 1 states that PPE and medical devices were still required to provide an adequate level of protection to users:

> "*Such measures should nevertheless not have a detrimental effect on the overall level of health and safety and all relevant stakeholders should ensure that any PPE or medical devices, which is being placed on the EU market, continues to provide an adequate level of protection of the users' health and safety*."

**D.4. Regulatory guidance issued by the UK Government**

31. Throughout the Covid-19 pandemic, the UK Government issued relevant guidance to suppliers of PPE and medical devices, as follows.

32. At the time of the Contract, the Government had issued version 3 of its "*Essential technical requirements for Gowns, gloves, masks, respirators, eye protection and coveralls where no CE mark has been obtained or where an alternative use is proposed of an existing CE marked product*" (the "**ETS**"). The ETS was "*Guidance*" within the meaning of the Contract, and therefore formed part of the Contract. The ETS included the following guidance:

32.1. The ETS guidance was aimed at those who wanted to make and supply high volumes of PPE and medical devices for direct Government procurement, and the items did not have a CE mark or the supplier wished to propose the alternative use of an existing CE marked product (p. 1). In this case, PPE Medpro proposed to sterilise non-sterile, surgical gowns and to sell them to DHSC as sterile surgical gowns.

32.2. The ETS guidance explained that PPE or medical devices could satisfy the essential requirements mandated by legislation through various routes, including by the manufacturer obtaining a derogation and/or by adopting any available technical solutions (pp 2-3).

32.3. The ETS guidance also stated that meeting the essential safety requirements set out in the applicable legislation would not guarantee clearance by the MHRA and that the MHRA would carry out robust scrutiny before allowing products to be supplied to the UK (pp 3-4).

32.4. The ETS guidance set out specifications for sterile surgical gowns, including

that they were to be validated as sterile with a Sterility Assurance Level ("**SAL**") of $10^{-6}$. It also explained that such items were subject to relevant standards BS EN 13795-1:2019, as regards the clothing's requirements, and BS EN 556-1:2001, as regards terminal sterilisation,[1] or equivalent technical solutions (p. 11).

33. It follows from the matters pleaded in this section D that, in order to comply with the terms of the Contract, the Gowns required either a valid CE accreditation or a 'derogation' from the MHRA (which at all material times was the agency responsible for derogations in respect of medical devices). As set out in section F.1.2 below, at all material times, PPE Medpro had (and has) neither of these.

## E. THE SUPPLY OF THE GOWNS BY PPE MEDPRO

34. The Gowns that PPE Medpro supplied were manufactured by one of the two factories identified in the Contract, being Wujiang Tutaike Textiles & Finishing Co. Ltd. DHSC understands that the Gowns were purportedly sterilised through exposure to radiation by third parties before being delivered to DHSC.

35. Despite the fact that PPE Medpro procured the manufacture of the Gowns by third parties, it was a "manufacturer" for the purposes of reg. 2 of the MDR 2002 in that it was:

35.1. The person with responsibility for the design, manufacture, packaging and labelling of the Gowns before they were placed on the market under its own name, regardless of whether these operations were carried out on its behalf by a third party; and/or

35.2. It assigned to the Gowns their intended purpose as a device before they were placed on the market under its own name.

36. PPE Medpro delivered the Gowns to DHSC in 72 lots, which were received into the UK between 20 August 2020 and 25 October 2020. Between 8 July 2020 and 28 August 2020, DHSC paid £121,999,219.20 to PPE Medpro.

37. The first inspections regarding deliveries of the Gowns took place on or around 11 September 2020. When the Gowns were inspected, it became clear that their CE

[1] I.e. where an item is sterilised in its final packaging.

markings did not include a notified body number, as required under the MDR 2002. Furthermore, in the meantime, PPE Medpro was involved in a separate PPE tendering exercise. During that exercise, it was found to have supplied a test report (numbered SHAT06648491) purporting to be from an entity called Intertek, but which Intertek denied having issued. As a result, PPE Medpro was referred to the MHRA's compliance unit for further investigation.

38. Alan Taylor, on behalf of, MHRA entered into correspondence with PPE Medpro from 4 November 2020, to enquire *inter alia* into why the Gowns had been supplied in packaging bearing a CE mark with no notified body number. By an email to Mr Taylor dated 6 November 2020, Mr Page explained that the Gowns did not have the requisite notified body accreditation in order to be CE marked.

39. On 17 November 2020, Mr Taylor responded to Mr Page explaining that the Gowns had been CE marked and were labelled as "Sterile R", despite there being no notified body number. Mr Taylor explained that, as a result, the CE mark should not have been affixed to the Gowns and that the stock could not be released from the Daventry warehouse for use by the NHS until the Gowns had the correct notified body certification.

40. PPE Medpro took no remedial action in respect of the Gowns and did not obtain a derogation from MHRA.

41. On 23 December 2020, DHSC sent a notice to PPE Medpro rejecting the Gowns, in accordance with Schedule 2, clauses 4.2 and/or 4.6 of the Contract (the "**Rejection Notice**"). The Rejection Notice explained that the Gowns had been rejected by DHSC because they did not comply with relevant laws applying to medical devices and because PPE Medpro had failed to provide certification to establish that the Gowns had been reliably sterilised for medical use, rendering them unusable in the NHS. The Rejection Notice required PPE Medpro to repay the Price to DHSC, and to collect the rejected Gowns at its own risk and expense, or to request that DHSC dispose of them at PPE Medpro's cost. The Rejection Notice also made clear that DHSC did not require replacements for rejected Gowns, and that any outstanding purchase obligation in relation to the Gowns were cancelled.

42. PPE Medpro has not repaid the Price, nor has it collected the Gowns. The Gowns remain in storage and cannot be repurposed because of their lack of sterility and the improper

CE labelling on their packaging. Accordingly, DHSC will have to dispose of or recycle them.

## F. DHSC'S CLAIMS AGAINST PPE MEDPRO

### F.1. PPE Medpro's breaches of the Contract

#### *F.1.1. The Gowns are not sterile or sterile to the contractual standard*

43. Pursuant to the guidance relating to sterile gowns contained in the ETS, the Gowns were contractually required to be sterile to the SAL set out in BS EN 556-1:2001 (either through compliance with that particular standard, or through an equivalent technical solution, as set out in the ETS). The SAL set out in BS EN 556-1:2001 is $10^{-6}$, which means that only one Gown in a million should not be sterile.

44. DHSC has commissioned independent aerobic and anaerobic sterility testing on 60 randomly sampled Gowns across three different batches of the Gowns to determine whether they meet the required SAL. The results of those tests are as follows:

    44.1. A total of 26 out of 30 tested Gowns were found not to be sterile in the aerobic tests, comprising all 10 Gowns in sample numbers 70200 and 70201, and 6 out of 10 Gowns in sample number 702199.

    44.2. A total of 29 out of 30 tested Gowns were found not to be sterile in the anaerobic tests, comprising all 10 Gowns in sample numbers 70200 and 70201, and 9 out of 10 Gowns in sample number 702199.

45. The results of DHSC's testing show that the Gowns do not comply with the SAL required by BS EN 556-1:2001. PPE Medpro therefore breached the Contract as follows:

**PARTICULARS**

    45.1. PPE Medpro breached the requirements in section 6 of the Order Form, and Sch. 2, cl. 1.3 and the term implied by s. 13(1) SGA 1979 in that it failed to supply gowns that were sterile, or sterile to the SAL required by BS EN 556-1:2001, as required by and described in the Contract.

    45.2. PPE Medpro breached Sch 1, cl. 12.2 and Sch. 2, cl. 1.1.5 in that it agreed to supply sterile gowns, but in fact supplied gowns that had not been sterilised to

the SAL required by BS EN 556-1:2001 in accordance with a suitable, effective and properly validated sterilisation method.

45.3. PPE Medpro breached Sch 2, cl. 7.1.1 and the term implied by s. 14(3) SGA 1979 in that the Gowns were not sterile, or sterile to the SAL required by BS EN 556-1:2001, and were therefore not suitable or fit for their intended purpose as sterile gowns, and not of satisfactory quality as sterile gowns.

45.4. PPE Medpro breached Sch 2, cl. 7.1.3 and the term implied by s. 14(2) SGA 1979 in that the Gowns were not manufactured with reasonable skill and care because they were not sterile, or sterile to the SAL required by BS EN 556-1:2001.

45.5. PPE Medpro breached Sch. 2, cl. 1.1.6, 7.1.1, 7.1.4, 7.1.19 and 14.1 in that the Gowns did not comply with "*Law*" or "*Guidance*" in the form of paragraph 1 of the Commission Recommendation or the ETS. The Gowns were not sterile to the SAL required by BS EN 556-1:2001 and therefore did not meet the standard set in the relevant Guidance. Further, because of this deficiency, the Gowns did not satisfy the essential requirements set out in Annex I to the Medical Devices Directive, sections 1, 3, 5, 8.3 and 8.4, and were therefore placed on the market and/or supplied by PPE Medpro in breach of reg. 8 of the MDR 2002, because:

(a) The Gowns were not manufactured in such a way that, when used as sterile Gowns in the NHS, they would not compromise the clinical condition or safety of patients (breaching section 1).

(b) The Gowns did not achieve the sterility performance intended by PPE Medpro and were not designed, manufactured or packaged (as to which, see paragraph 49 below) in such a way that they would be suitable for use as sterile gowns (breaching section 3).

(c) The Gowns were not manufactured and/or (it is inferred) packed (as to which, see paragraph 49 below) so as to ensure that they would be sterile when placed on the market and/or would remain sterile until the protective packaging was damaged or opened (breaching sections 5 and 8.3).

(d) It is inferred that the Gowns were therefore not manufactured and

sterilised by an appropriate, validated method (breaching section 8.4).

***F.1.2. The Gowns bear an invalid CE mark and do not benefit from a derogation***

46. By affixing a CE mark with no accompanying notified body number, PPE Medpro breached the following provisions of the MDR 2002:

**PARTICULARS**

46.1. PPE Medpro breached reg. 10(3) and/or (4) because it placed on the market and/or supplied the Gowns (each being a relevant device) with a CE marking that was not accompanied by a relevant notified body identification number as regards the sterility of the Gowns.

46.2. PPE Medpro breached reg. 13(1)(a) because it did not fulfil the applicable obligations imposed by section 5 of Annex VII to the Medical Devices Directive. In this regard, PPE Medpro did not use a sterilisation process in respect of the Gowns that had been audited or accredited by a notified body and has therefore been unable to provide the documentation and/or certification in respect of the sterilisation process required to affix a CE mark to the Gowns, as required by Annexes II (sections 3, 4 and 5), IV (section 4), V (sections 3 and 4) or VI (sections 1, 3 and 4) to the Medical Devices Directive.

46.3. PPE Medpro breached reg. 13(1)(b) because it affixed a CE marking to the Gowns without being able to declare that they met the applicable provisions of the Medical Devices Directive, for the reasons in paragraphs 45 and 46.2 above.

46.4. PPE Medpro breached reg. 13(1)(c) because it affixed a CE marking to the Gowns without ensuring that they met the provisions of the Medical Devices Directive, for the reasons in paragraph 45.5 above.

47. By affixing a CE mark with no accompanying notified body number, PPE Medpro breached the Contract as follows:

**PARTICULARS**

47.1. PPE Medpro breached Sch. 1, cl. 12.2, Sch. 2, cl. 1.1.6, Sch. 2 cl. 7.1.19 and Sch. 2, cl. 14.3 because the Gowns were not supplied in accordance with the relevant requirements of the MDR 2002, as set out under paragraph 46 above.

47.2. PPE Medpro breached Sch. 1, cl. 12.3.1 because the appropriate conformity assessment procedures required by Annex VII (section 5) to the Medical Devices Directive as regards the Gowns' sterility were not followed. In this regard, PPE Medpro did not use a sterilisation process in respect of the Gowns that had been audited or accredited by a notified body and has therefore been unable to provide the documentation and/or certification in respect of the sterilisation process required to affix a CE mark to the Gowns, as required by Annexes II (section 3, 4 and 5), IV (section 4), V (sections 3 and 4) or VI (sections 1, 3 and 4) to the Medical Devices Directive.

47.3. PPE Medpro breached Sch. 1, cl. 12.3.2, 12.3.4 and cl. 12.8 because the relevant declarations of conformity or EC-type examination certificates required by the Medical Devices Directive and/or the Contract as regards the Gowns' sterility were not in place prior to their delivery to DHSC. In this regard, PPE Medpro did not use a sterilisation process in respect of the Gowns that had been audited or accredited by a notified body and has therefore been unable to provide the documentation and/or certification in respect of the sterilisation process required to affix a CE mark to the Gowns, as required by Annexes II (section 3, 4 and 5), IV (section 4), V (sections 3 and 4) or VI (sections 1, 3 and 4) to the Medical Devices Directive.

47.4. PPE Medpro breached Sch. 1, cl. 12.3.3, cl. 12.7 and Sch. 2, cl. 14.1 and 14.4 because the CE mark was not affixed to the Gowns in accordance with the MDR 2002, as set out under paragraph 46 above.

47.5. PPE Medpro breached Sch. 2, cl. 7.1.1 because the Gowns were not suitable for the purpose set out in the Order Form and/or fit for their intended purpose, being use as sterile surgical gowns, and did not comply with the standards and requirements set out in the Contract, because they bore an invalid CE mark (for the reasons set out under paragraph 46 above) and therefore cannot be used.

47.6. PPE Medpro breached Sch. 2, cl. 1.4 and 7.1.17 because it did not use a sterilisation process audited or accredited by a notified body, as required by Annexes II (section 3, 4 and 5), IV (section 4), V (sections 3 and 4) or VI (sections 1, 3 and 4) to the Medical Devices Directive, and it therefore has not obtained relevant accreditations to supply CE marked sterile surgical Gowns.

47.7. PPE Medpro breached Sch. 2, cl. 7.2 and 7.2.1 because the Gowns were not validly CE marked for the reasons set out under paragraph 46 above.

48. Further, PPE Medpro did not obtain a derogation pursuant to reg. 12(5) in respect of the Gowns' being placed on the market, despite not bearing a proper CE mark as regards their sterility. PPE Medpro therefore breached the Contract as follows:

**PARTICULARS**

48.1. PPE Medpro breached Sch. 1, cl. 12.3.2, Sch. 2, cl. 7.1.16 and/or Sch. 2, cl. 7.1.17 because it did not have a necessary approval to supply the Gowns.

48.2. PPE Medpro breached Sch. 2, cl. 1.4 because it did not have all relevant consents or authorisations required to supply the Gowns prior to delivery.

48.3. PPE Medpro breached Sch. 2, cl. 7.2.1 because it did not have all relevant authorisations or approvals relating to the sale, manufacture, distribution, supply or delivery of the Gowns.

48.4. PPE Medpro breached Sch. 2, cl. 1.1.6, 7.1.16, 7.1.19, 7.2 and 7.2.1 because it did not obtain a derogation in accordance with the ETS.

***F.1.3. Non-compliant packaging***

49. In breach of the requirements contained in Annex A1 (set out in paragraph 12 above), PPE Medpro supplied single-wrapped Gowns in a polythene bag sealed at the top, rather than double-wrapped Gowns in peel-away packaging.

**F.2. Unjust enrichment**

50. DHSC paid the Price to PPE Medpro on the basis that it would receive Gowns that complied with the Contract and could therefore be used as medical devices in the NHS.

51. For the reasons set out in paragraphs 43 to 49 above, the basis for the transfer of the Price from DHSC to PPE Medpro has failed. PPE Medpro has therefore been unjustly enriched at DHSC's expense and is liable to repay the Price to DHSC.

## G. REMEDIES

### G.1. Repayment of the Price and reimbursement of costs

52. As set out in paragraph 41 above, DHSC sent the Rejection Notice to PPE Medpro and rejected the Gowns, pursuant to Sch. 2, cl. 4.2 and/or 4.6 of the Contract. Pursuant to Sch. 2, cl. 4.5, PPE Medpro is required to refund any sums paid for the Gowns along with any costs reasonably incurred by DHSC as a result of any such rejection within 30 days of the Rejection Notice. PPE Medpro has not taken such steps.

53. Further, or alternatively, Sch. 1, clauses 12.2, 12.3, 12.7 and/or 12.8, and/or Sch. 2 clauses 1.1.6, 1.4, 7.1.1, 7.1.16, 7.1.17, 7.1.19, 7.2, 14.1, 14.3 and/or 14.4, or any of them, were conditions by reason of their nature, subject matter and in the circumstances of the Contract. Accordingly, DHSC is entitled to (and by its Rejection Notice did) treat the Contract as discharged by PPE Medpro's breaches referred to in paragraphs 43 to 49 above.

54. DHSC therefore claims payment of the following sums from PPE Medpro:

    54.1. £121,999,219.20, being repayment of the Price DHSC paid in return for the Gowns;

    54.2. £6,893,373.00 in respect of DHSC's reasonably estimated storage costs incurred in relation to the Gowns;[2] and

    54.3. £4,685,328.00, being the reasonably estimated cost of disposing of the Gowns.

55. Further or alternatively, DHSC claims repayment of the Price by way of restitution for the unjust enrichment pleaded at paragraphs 50 and 51 above.

### G.2. Indemnity and/or damages for breach of contract

56. As a result of PPE Medpro's breaches of the Contract set out in paragraphs 43 to 49 above, the MHRA will not release the Gowns from storage and DHSC is unable to use them in the NHS as sterile surgical gowns and/or they cannot be used within the NHS for any purpose. Accordingly, PPE Medpro's breaches of the Contract have caused loss

[2] For present purposes, DHSC has estimated its storage costs from 23 December 2020, the date of the Rejection Notice, until the date of these Particulars of Claim. DHSC reserves the right to give further particulars of, or to amend, this figure to reflect its full loss in respect of storage costs.

and damage to DHSC.

57. Pursuant to Sch. 2, cl. 7.3, PPE Medpro agreed to indemnify DHSC and to keep it indemnified against any loss, damages, costs and expenses (including legal costs and expenses) suffered or incurred by DHSC as a result of a breach of Sch. 2, cl. 7.2 of the Contract.

58. DHSC therefore claims an indemnity caused by PPE Medpro's breach of cl. 7.2, and/or damages for all of PPE Medpro's breaches of the Contract, in respect of the following losses, damages, costs and/or expenses:

58.1. £121,999,219.20, being the Price DHSC paid in return for the Gowns;

58.2. £6,893,373.00 in respect of DHSC's reasonably estimated storage costs incurred in relation to the Gowns, and its further storage costs until disposal, which continue to be incurred at a weekly rate of £61,313.36;[3] and

58.3. £4,685,328.00, being the reasonably estimated costs of disposing of the Gowns.

59. DHSC therefore claims a total of £133,577,920.20 and its further storage costs up to disposal under Sch. 2, cl. 7.2 and/or as damages.

**G.3. Interest**

60. DHSC claims interest on the sums set out above at such rate or rates, and for such period or periods as the court thinks fit, pursuant to s. 35A of the Senior Courts Act 1981.

**AND THE CLAIMANT CLAIMS:**

(1) Repayment of £121,999,219.20, being the Price paid for the Gowns, and payment of £11,578,701.00 in respect of DHSC's reasonably incurred costs.

(2) Further or alternatively, payment of £133,577,920.20, pursuant to the indemnity under Sch. 2, cl. 7.3 of the Contract.

(3) Further or alternatively, damages of £133,577,920.20.

(4) Further or alternatively, restitution of £121,999,219.20, being the Price paid for the

[3] Footnote 2 above is repeated.

Gowns.

(5) Interest.

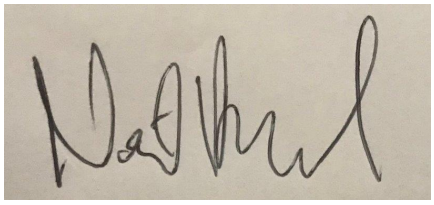
(6) Further or other relief.

(7) Costs.

**TOM WEISSELBERG KC**
**TIRAN NERSESSIAN**
**ALBERT SAMPSON**
**NICHOLAS WRIGHT**

**STATEMENT OF TRUTH**

The Claimant believes that the facts stated in these Particulars of Claim are true. The Claimant understands that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.



Signed

Full Name: NEIL BEARD

Date: 19 DECEMBER 2022

Position: JUDICIAL REVIEW MANAGER

For and on behalf of the Claimant