RESPONSES TO
PPE MEDIA COVERAGE

2020 - 2021

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CAPITAL

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Statement regarding National Audit Office (NAO) report into PPE Supply

25 November 2020

Ayanda is pleased to note that the NAO report issued today confirms that the FFP2 respirator masks ordered by the DHSC and delivered:

1. were of the design that was agreed; and
2. complied with the BS EN149 standard.

It is very disappointing that it appears that NHS will not use Ayanda FFP2 masks only because of a DHSC policy decision not to use ear loop designs based on tests of other vendor's product not because of any fault with the masks supplied by Ayanda. We remain confident that our masks are fit for use by NHS workers and these masks are currently in use by other healthcare systems in Europe and across the world.

The BS EN149 standard allows for use of ear loops and head straps under the generic term "Head Harness". Initial DHSC guidance on the standard did not explicitly exclude ear loop designs and on 5 May 2020 DHSC clarified its guidance to allow for ear loops as per BS EN149.

The FFP2 masks supplied by Ayanda were fully certified by British Standards Institute (BSI) as compliant with BS EN149:2001+A1:2009 and EU Regulation 2016/425 as amended by Commission Recommendation (EU) 2020/403 for the period of the Covid 19 pandemic, and BSI confirmed that the masks fulfilled the essential health and safety requirements set out in Annex II of EU Regulation 2016/425. They are therefore fit for use by frontline NHS workers.

All of Ayanda's FFP2 masks have been delivered to schedule and no product has been rejected by DHSC as was allowed for in the contract.

DHSC has not supplied any evidence to Ayanda that its masks failed any tests (including fit tests) that might have been carried out by the Health & Safety Executive. Ayanda has written to the Government Legal Department providing all technical documentation demonstrating that its masks are fully compliant and fit for use by NHS.

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Response to comments made at PMQs and the NAO Report on PPE Procurement 16 November 2020

Ayanda today wrote to the Prime Minister, Boris Johnson, the Health Secretary Matt Hancock and Keir Starmer, the leader of the opposition in response to erroneous statements made in the House of Commons regarding Ayanda's supply of FFP2 masks to the DHSC/NHS. The National Audit Office also refused to publish our clarifications in full regarding the status of the masks in their report to be published shortly. The full facts are set out in the letter which is included overleaf.

AYANDA CAPITAL

To:
The Right Honourable Boris Johnson
Prime Minister
10 Downing Street
London SW1A 2AA

Date:
16 November 2020

Dear Prime Minister

Ayanda Supplied FFP2 masks

I am writing to you following various questions raised in the House regarding the supply of FFP2 masks by Ayanda Capital Limited ("Ayanda") and the allegations being recklessly bandied about by The Good Law Project and The Times Newspapers that the FFP2 masks supplied by Ayanda are "unusable".

To clarify:

1. The masks supplied met the requirements of the DHSC's specification (BS EN149:2001 + A1:2009).

2. The masks were supplied as PPE intended for use in healthcare under the European derogation 2020/403 from PPE Regulation (EU) 2016/425.

3. The masks were approved by the Cabinet Office PPE procurement Technical Assurance team.

4. The masks ordered were specifically of an ear loop design, as allowed under the relevant standard (BS EN149:2001 + A1:2009) and the essential health and safety standards in Annex II of Regulation (EU) 2016/425.

5. This was confirmed in paragraphs 52 and 58 of the Secretary of State's Summary Grounds for Resisting the Judicial Review claim brought by The Good Law Project and Every Doctor dated 25 August 2020.

6. The Government Legal Department has been unable or unwilling to supply any evidence that our masks were either tested by HSE or failed any tests that may have been carried out and they are therefore safe to be used by the NHS.

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7. The masks have all been supplied and paid for under the terms of Ayanda's contract with DHSC and no product has been rejected – as could have been the case under the contract had our product not been compliant.

8. Suggestions that the masks are not fit for purpose or are somehow unsafe to use by frontline NHS workers are simply untrue and we are advised defamatory.

We hope this clarifies the matter. I would be happy to supply further information should you require further clarification. I have copied this letter to Matt Hancock, the Secretary of State and the Right Honourable Keir Starmer MP.

Yours respectfully

Tim Horlick

CEO, Ayanda Capital Limited

AYANDA CAPITAL

BSI Test Report on Ayanda Supplied FFP2 Masks

November 2020

The Times has continually repeated untrue allegations fabricated by Jolyon Maugham that the FFP2 masks supplied by Ayanda did not meet required technical standards. These allegations are entirely false. Overleaf is a full copy of the independent test report submitted to DHSC as part of the Technical Assurance process carried out by DHSC. This report confirms that the masks meet the technical specification in all respects and specifically with regard to 1) head harness comfort and 2) the security of the fastenings.

Test Report 3201476.

Zhende Medical Co., Ltd

Introduction.

This report has been prepared by Paul Waller and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3201476**	Zhende Medical Co., Ltd
Job type:	Testing Samples Submitted	Gaobu Town
Start Date:	14/04/2020	Shaoxing
Test type:	Type	Zhejiang
Sample ID:	10189486	312035
Registration:	**CE 728114**	China
Scheme:	Negative pressure RPE	
Protocol:	PP123	
Scheme Mgr:	Nathan Shipley	

The report has been approved for issue by T Wicksey – Senior Test Engineer

Approved For Issue	
	Issue Date: 23 April 2020

Objectives.

This is an independent test evaluation to only certain clauses or sub-clauses of the agreed specification in accordance with the following test programme:

BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers

Product Scope.

COVID-19 masks for use by healthcare workers

Report Summary.

The samples were received on 14 April 2020 and the testing was started on 14 April 2020.

The samples submitted complied with the requirements of the test work conducted.

Test Samples.

Sample ID	ER Number	Description
1 to 19	10189486	Mask N9501F FFP2

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Mask N9501F FFP2

Test Requirements.

Testing in accordance with BSI COVID-19 filtering face piece technical specification
Technical testing specification for COVID-19 masks for use by healthcare workers

EN 149:2001+A1:2009 Performance requirement	EN 149:2001+A1:2009 Test method clause	Requirement	Assessment
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. *2 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.4.	During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.	Pass
7.9 Leakage **7.9.1 Total inward leakage** *5 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.5.	All samples must achieve All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)	Pass
7.9 Leakage **7.9.2 Penetration of filter material** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test*	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
7.12 Carbon dioxide content of the inhalation air *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.7.	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Pass
7.16 Breathing resistance *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of; 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories
Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.
Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.
Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.
Fail: Non-compliance. Product does not meet the requirements of this clause.
Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.
N/T: Not Tested
N/A: Not Applicable
AR: As Received
TC: Temperature Conditioned
SW: Simulated Wear
FT: Flow Tested
MS: Mechanical strength
MMDF: Manufactures Minimum Design Flow
MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

Should you wish to speak with BSI in relation to this report, please contact Customer Services on +44 (0)8450 80 9000.

BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ

UKAS TESTING
0135

Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.
Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Results.

Testing in accordance with BSI COVID-19 filtering face piece technical specification

BS EN 149:2001 +A1:2009 Technical testing specification for COVID-19 masks for use by healthcare workers

CLAUSE	REQUIREMENTS	ASSESSMENT
7.7	**Practical performance** The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Test in accordance with clause 8.4 of the standard. ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:* *a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.*	Pass

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
JB2	1 AR	OK	OK	OK	None	Pass
LM2	2 AR	OK	OK	Good	None	Pass

7.9	**Leakage**	
7.9.1	Total inward leakage The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. Test in accordance with clause 8.5 of the standard. ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *5 test subjects, masks tested 'As received'. All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2).*	Pass

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)						Assessment
			A	B	C	D	E	Average	
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking		
SR1	3	AR	3.4531	3.1778	3.7684	2.5203	3.1368	3.2113	Pass
SI1	4	AR	0.6113	0.7683	0.9273	2.3936	1.6803	1.2762	Pass
LM2	5	AR	1.2270	1.7870	2.2870	1.3890	3.2581	1.9896	Pass
JW1	6	AR	0.7323	1.4311	1.0974	1.2897	1.8460	1.2793	Pass
JT1	7	AR	2.7729	3.3930	3.4078	2.3022	1.9829	2.7718	Pass

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9.2	Penetration of filter material ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3 min test. Testing shall be done in accordance with 8.11. 6% limit for both PO and NaCl*	Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
8	AR	95	< 6	0.83
9	AR			0.67
10	AR			1.23

Table D: Clause 8.11 - Paraffin oil penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
11	AR	95	< 6	4.18
12	AR			4.25
13	AR			4.75

7.12 Carbon dioxide content of inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume). Pass

Test in accordance with clause 8.7 of the standard.

Table E: Clause 8.7 - Carbon Dioxide content of the inhalation air

Sample	Pre-test condition	Dead space CO_2 (%)	
		Limit	Measured
14	AR	< 1.0	0.64
15	AR		0.59
16	AR		0.54

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	**Breathing resistance** ***Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers*** *3 test samples masks tested 'As received'. Test in accordance with clause 8.9 of the standard.* *The breathing resistances shall meet the requirements of FFP2;* *30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)*	Pass

Table F: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow

Sample	Pre-test condition	Continuous flow (l/min)	Inhalation resistance (mbar)	
			Limit	Measured
17	AR	30	< 0.7	0.41
18	AR			0.43
19	AR			0.40
17	AR	95	< 2.4	1.28
18	AR			1.30
19	AR			1.25

Table G: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the worst case reported

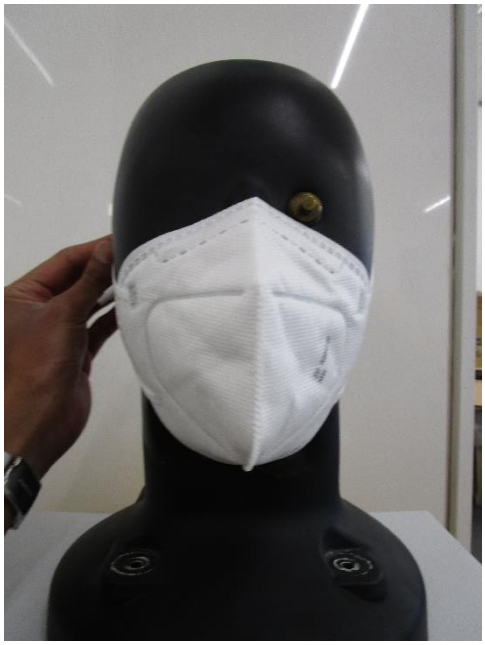
Sample	Pre-test condition	Continuous flow (l/min)	Exhalation resistance (mbar)	
			Limit	Measured
17	AR	160	< 3.0	2.09
18	AR			2.03
19	AR			2.11

Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
JB2	114	144	108	59	574	Male
SI1	121	135	142	48	575	Male
JW1	116	126	122	48	570	Male
JT1	130	140	118	44	589	Male
SR1	118	133	130	52	585	Male
LM2	110	148	125	44	589	Male

Note: All candidates were clean shaven

Product photographs.



Front View

Side View

Inside View

*** End of Report ***

AYANDA CAPITAL

Further Statement regarding inaccurate and untrue allegations made by The Times article dated 06.08.2020 on PPE

Below is the text of a letter sent to the legal departments of all major media outlets clarifying and correcting The Times allegations:

TEXT OF LETTER TO LEGAL DEPARTMENTS OF MAJOR MEDIA OUTLETS

This letter is in response to the various articles published by The Times and in particular the article in The Times dated 6 August 2020 regarding the supply of PPE to DHSC by Ayanda Capital Limited ("Ayanda") under the heading "Ministers waste £150m buying unusable masks from banker".

Several inaccurate and misleading assertions have been made by The Times and this note seeks to correct and clarify those inaccuracies.

The Times article stated that the masks supplied are "unusable" or that "there are concerns that they cannot be fixed securely".

The FFP2 masks supplied to DHSC by Ayanda were subject to a rigorous due diligence process by DHSC's Technical Assurance team and approved by them.

The Government published specifications for masks online. These specifically referred to the European standards for FFP2 masks called BS EN149:2001+A1:2009. The masks supplied by Ayanda meet all these requirements and comply with all EU requirements for these type of masks.

The Government also published clarification of their standards saying that masks "should" have headbands rather than ear loops where possible but that it was not a requirement that they "must" have such fixings.

In its response to Good Law Project's (GLP) Judicial Review claim, the Government Legal Department (GLD) stated that "head loops are not a requirement of the relevant FFP2 technical standard…and are accepted by other countries".

In addition, GLD has confirmed that the masks meet the requirements of the relevant FFP2 standard (BS EN149:2001+A1:2009).

AYANDA CAPITAL

All the masks have been manufactured and either delivered or made available for collection to DHSC.

Under the terms of our contract the DHSC had 30 days to inspect and accept or reject each delivery of masks. The DHSC has not rejected any of our masks nor has it informed Ayanda that its masks are unusable, unsafe or cannot be fixed securely.

At no point has anyone in Government or DHSC ever suggested to Ayanda that the masks are unusable, do not meet the required standards or are unsafe in any way.

On 1 July a member of the Cabinet Office PPE Procurement team contacted Ayanda and asked if the remaining FFP2 masks that had not been delivered could be swapped from "ear loop" design masks to "Headband masks" as these had become the preferred design. The reason given was that some people found ear loop masks "uncomfortable". As far as we are aware, this applied to all ear loop masks delivered by all vendors to DHSC. No mention was made that the masks were "unusable", "cannot be fixed securely" or were unsafe in any way.

As 47m of the 50m masks had already been manufactured Ayanda offered at its own cost to switch the remaining 3m masks to headband masks or swap them for a much larger volume of cheaper Type IIR masks as DHSC now had a greater requirement for Type IIR masks.

Ayanda remains mystified as to why DHSC seems to now be suggesting these masks are unusable and is seeking urgent clarification for GLD as to the basis of this assertion.

Regardless of the NHS' recently declared preference for headband fixings the masks supplied by Ayanda can be used by any public sector worker so there has been no money wasted.

AYANDA CAPITAL

Response to The Times article dated 06.08.2020 on PPE

07 August 2020

Ayanda Capital yesterday wrote to the editor of The Times requesting publication of our clarifications of the inaccurate and misleading comments made by The Times in respect of Ayanda's PPE contract with DHSC. The Times has chosen not to publish this letter. The letter can be read in full overleaf.

AYANDA CAPITAL

To:

The Editor

The Times

By email:

letters@thetimes.co.uk

Date:

6 August 2020

Dear Sir

I am writing in response to the article in The Times today regarding the supply of PPE to DHSC by Ayanda Capital Limited under the heading "Ministers waste £150m buying unusable masks from banker".

It is simply incorrect to state that the masks supplied are "unusable" or that "there are concerns that they cannot be fixed securely".

As I pointed out to your journalist before this article was published, the masks supplied were subject to a rigorous due diligence process by DHSC's Technical Assurance team and approved by them. The masks meet all the required standards under both the DHSC's own specifications and EU law. All the masks have been manufactured and delivered to DHSC and none have been rejected by DHSC, as DHSC would have been able to do under the terms of our contract if the masks were faulty.

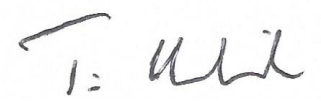
In direct contradiction to the statement in your article, the Government Legal Department has confirmed that the masks meet all the required standards.

At no point has anyone in Government or DHSC ever suggested to Ayanda that the masks are unusable, do not meet the required standards or are unsafe in any way.

It is true to say that towards the end of our contract DHSC asked to swap a portion of the "ear loop" design masks for "Headband masks" as these had become the preferred design. However, the entire stock of masks supplied by Ayanda to DHSC remain available for use by key workers.

To conclude, the Government has not wasted any money in purchasing these masks and they are not unusable in any way. I trust this clarifies matters.

Yours sincerely



Tim Horlick

CEO, Ayanda Capital Limited