PPE TECHNICAL FILE:	TFK95/Med
Model:	KN95(NR)/FFP2 Medical Particulate Respirator Disposable Non-Sterile (Face Mask)
Regulation:	PPE Regulation (EU) 2016/425
Manufacturer:	Medical Devices Technology International Ltd, The Kace Building, Victoria Passage, Wolverhampton WV1 4LG, West Midlands, United Kingdom
Critical Sub-contractor:	Guangdong Donghua Optoelectronics Technology Co. Ltd, Kengkou Industrial Zone, Dean Village, Houjie Town, Dongguan, Guangdong, China

Section 1

File Contents List

Section 2

Amendment Record Sheet

Date of Revision	Details of change	Revision Number
30/05/2020	First issue of technical file TFKN95/Med.	Draft first issue
10/06/2020	Inclusion of Mod B Notified Body details, including address and NB number as part of User Information, inclusion of Module B cert no. CE 730967 and Module C2 CE 730969	02
24/07/2020	Modification to mask to improve TIL at page 6, Change to product model number at pages 4, 9 & 11, Model change to KN95/FFP2 on pages 1, 4, 9, 10 & 11, Change of EAN on page 10, Up date of component parts on page 7	03
24/07/2020	New change control of document	03
07/09/2020	Inclusion of BSI test report	04
08/09/2020	Update of Technical file to correct action identified under CAR1, CAR2, CAR3, CAR4, CAR5, CAR6, CAR7 – all corrective actions high lighted in blue	05
09/09/2020	Design dimension of face mask pages 6 & 7	05 issue 1.6
09/09/2020	Inclusion of Raw material Manufacturers' details page 9	05 issue 1.6
09/09/2020	Inclusion of Product Markings details page 21	05 issue 1.6

Section 3

Product Description

Model Name: MODEL KN95 (NR)/FFP2

This Product is a disposable single use face mask ensuring protection against particulate hazards used for prevention and protection against harmful biological agents such as viruses, falling within the scope of the Regulation (EU) 2016/425 and repealing Council Directive 89/686/EEC.

Product Codes: 4020

Main description: This particulate respirator (face mask) is made from 4layer fabric that include melt blown non-woven. It is a single use disposal half mask manufactured for COVID protection only

Variations: Model comes in one colour; white (W).

Classification: Category III (FFP2) according to PPE Regulation, as applicable to medical use.

Technical Standard: BSI's PPE for Healthcare Professionals 2020/403 -Respiratory Protective Equipment to be included.

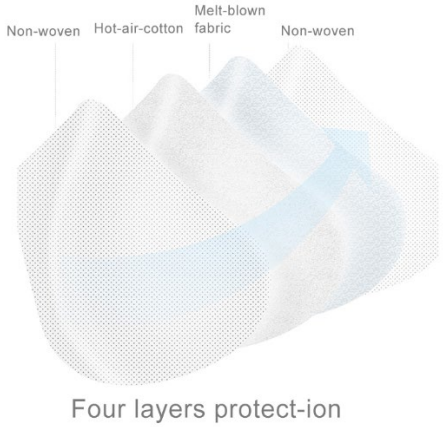
Intended use: This product is designed for clinical use only against particulate hazards used for prevention and protection against harmful biological agents such as viruses. This filtering half mask is manufactured for COVID-19 protection only. This filtering half mask is not a PPE device for general use and shall not be used for purposes other than protection against Covid-19.

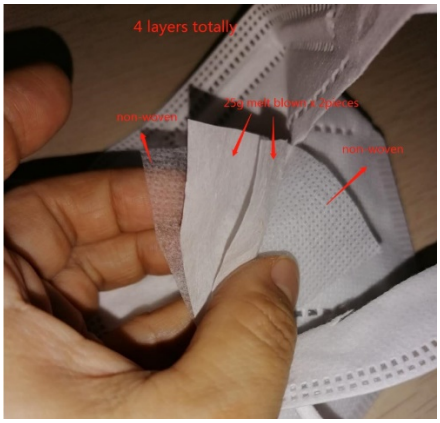
Applicants Details: Medical Devices Technology International Limited, The Kace Building, Victoria Passage, Wolverhampton WV1 4LG, West Midlands, United Kingdom

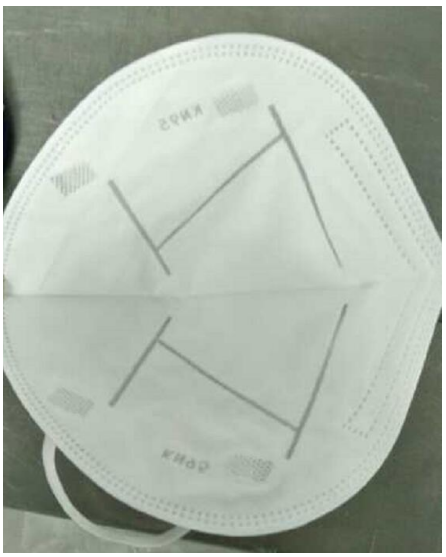
Factory Location: Guangdong Donghua Optoelectronics Technology Co. Ltd, Kengkou Industrial Zone, Dean Village, Houjie Town, Dongguan, Guangdong, China

Section 4

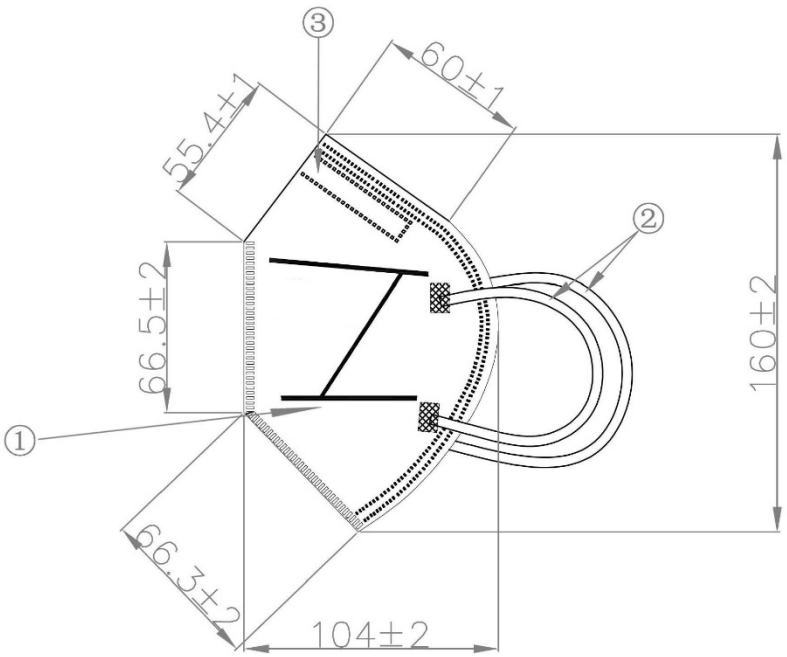
Product Images



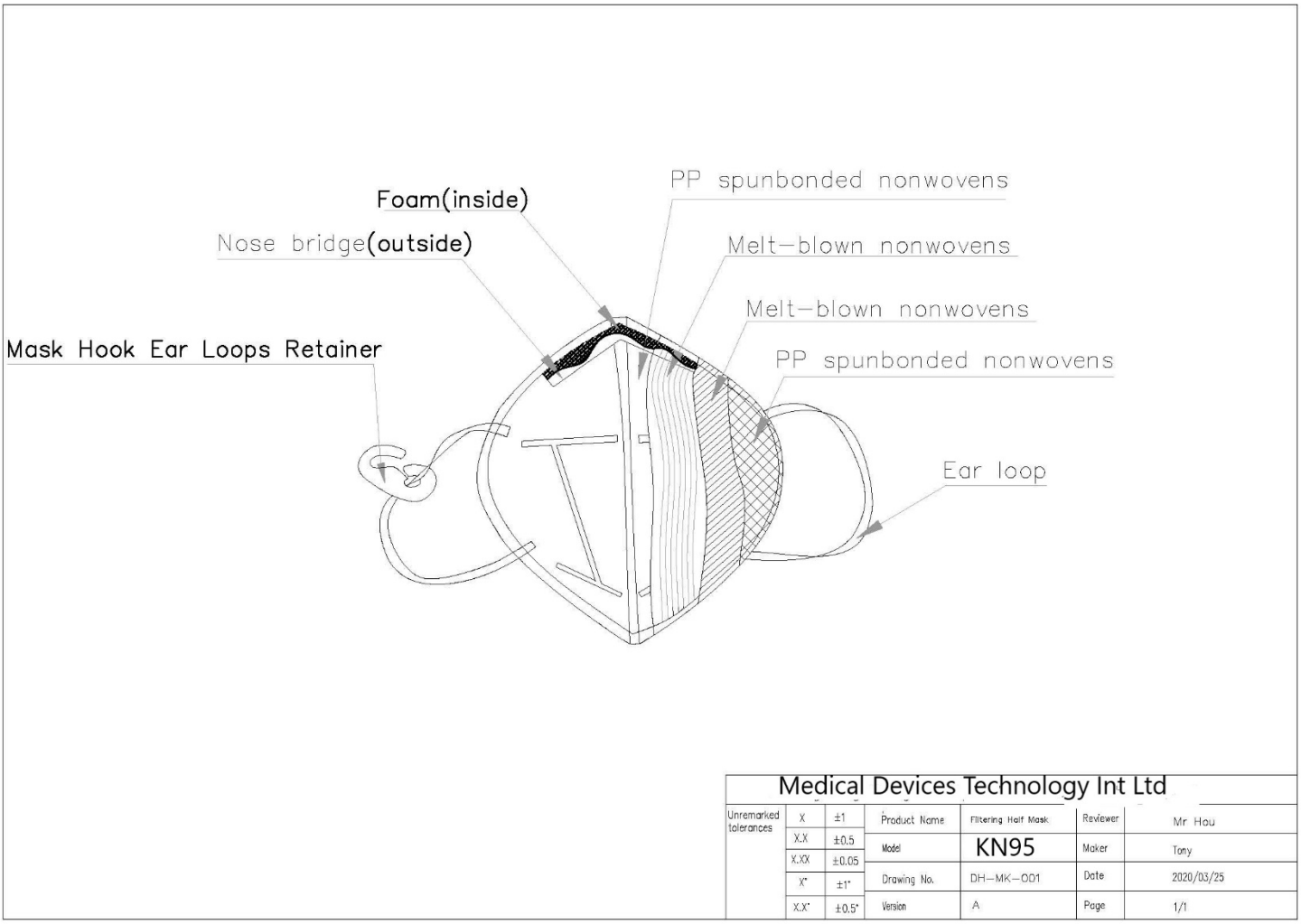




Dimension of Masks



Medical Devices Technology Int Ltd.						
Unremarked tolerances	X	±1	Product Name	Particle Filtering Half Mask	Reviewer	Mr Hou
	X.X	±0.5	Model	KN95	Maker	Tony
	X.XX	±0.05	Drawing No.	DH-MK-001	Date	2020/03/25
	X°	±1°	Version	A	Page	1/1
	X.X°	±0.5°				

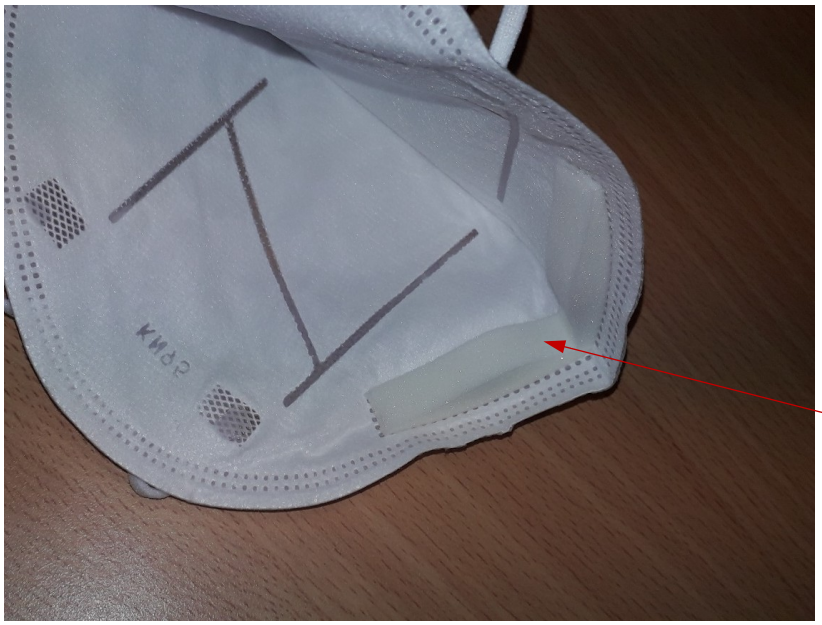


Medical Devices Technology Int Ltd						
Unremarked tolerances	X	±1	Product Name	Filtering Half Mask	Reviewer	Mr Hou
	X.X	±0.5	Model	KN95	Maker	Tony
	X.XX	±0.05	Drawing No.	DH-MK-001	Date	2020/03/25
	X°	±1°	Version	A	Page	1/1
	X.X°	±0.5°				

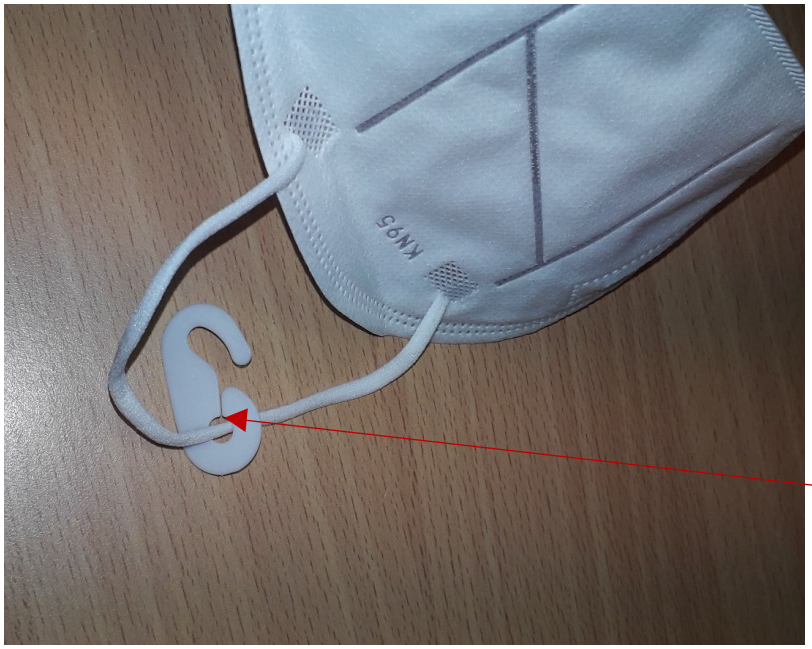
Section 4

Product Images

Improvement to Mask



Incorporation of foam at the inner part of mask at bridge of nose section; from the outside of mask the bridge bar across the nose can be pressed to give a firmer seal from the outer to inner surface thus reducing likelihood of inward leakage to this area of the mask



Single plastic clip added to one of ear loop, this clip can be applied to allow the user to pull ear loops together and clip behind the head thus pulling the face of mask more tightly around user's face, as reducing inward leakage from the side of face of the mask. Improving the sealing to side of the mask and the face.

Section 5

List of Components

Component	Material	Specification
1st Layer	Fabric	50g non-woven
2nd Layer	Fabric	25g melt brown
3rd Layer	Fabric	25g melt brown
4th Layer	Fabric	30g non-woven
Ear loops	Elasticated Fabric	
Shaped white foam	Fabric	
Hook Clip White	Plastic	

Raw Material Manufacturers' Details

List of Main Materials

Date : 2020-05-12

	COMPONENT OR SUB-COMPONENT	MATERIAL	GRADE	Supplier
1	Outer Cover	PP Spunbond nonwovens	50gsm （± 0.3 gsm)	Dongguan Xinyuan Non-woven Cloth Co.,Ltd.
2	Filters	Melt-blown nonwovens	25gsm (± 0.2 gsm)	Baoji Gerui Non-woven Cloth Co.,Ltd.
3	Inner cover	PP Spunbond nonwovens	30gsm (± 0.2 gsm)	Dongguan Xinyuan Non-woven Cloth Co.,Ltd.
4	Ear loop	Nylon+Spandex	W3.5 mm (± 0.5 mm) L190 mm （± 2 mm)	Dongguan Limei Packaging Materials Co., Ltd
5	Nose bridge	PE+Iron wire (double core)	4.0 mm (± 0.3 mm)	Dongguan Guhang Electronics Co., Ltd.
6	Foam	PPG+TDI	9 cm (± 1.0 cm)	Dongguan Shengren Packing Material Co., Ltd.
7	Mask hook Ear Loops Retainer	Silicone	3.5 cm （± 0.1 cm)	Xin Bo Mei Technology (Shenzhen) Co., Ltd.

Section 6

Test Reports

BSI Test Report 3224583 contained within this section.

Test Report 3224583.

Medical Devices Technology International Limited

Introduction.

This report has been prepared by O. Refoyo and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3224583**	Medical Devices Technology International Limited
Job type:	Testing Samples Submitted	Kace Building
Start Date:	10/07/2020	Victoria Passage
Test type:	Type	Wolverhampton
Sample ID:	10191757 / 10192183 / 10192243	WV1 4LG
Registration:	**CE 730967**	United Kingdom
Scheme:	Negative pressure RPE	
Protocol:	PP123	
Scheme Manager:	Nathan Shipley	

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

Approved For Issue	
	Issue Date: 4 September 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 26 June 2020 and the testing was started on 10 July 2020.

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

Test Samples.

Sample ID	ER Number	Description
1 to 19	10191757 / 10192183 / 10192243	Model: KN95 face mask

Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: KN95 face mask, vertical fold flat.

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.	At least 23 out of the 25 individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, at least 4 out of the 5 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	
JS2	1 AR	OK	OK	OK	None	Pass
MN1	2 AR	OK	OK	OK	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'. At least 23 out of the 25 individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, at least 4 out of the 5 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		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	
AA1	3	AR	0.4568	0.7093	0.5367	0.3315	0.5148	0.5098	Pass
CB1	4	AR	7.6324	11.0088	7.8381	2.8890	5.8279	7.0392	Pass
RS1	5	AR	3.4255	3.5319	3.5295	1.0417	3.4373	2.9932	Pass
SI1	6	AR	2.6874	4.6418	3.1634	3.0942	2.3940	3.1981	Pass
JA1	7	AR	0.8285	0.9085	0.7299	0.9518	1.0215	0.8881	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	0.1115
9	AR			0.1882
10	AR			0.2419

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	0.3305
12	AR			0.3725
13	AR			0.3750

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	0.55
15	AR		0.55
16	AR		0.50

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.	Pass
	The breathing resistances shall meet the requirements of FFP2; *30l/min – 0.7mbar (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)*	

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	0.35
18	AR			0.38
19	AR			0.33
17	AR	95	< 2.4	1.17
18	AR			1.25
19	AR			1.07

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	1.92
18	AR			1.89
19	AR			1.72

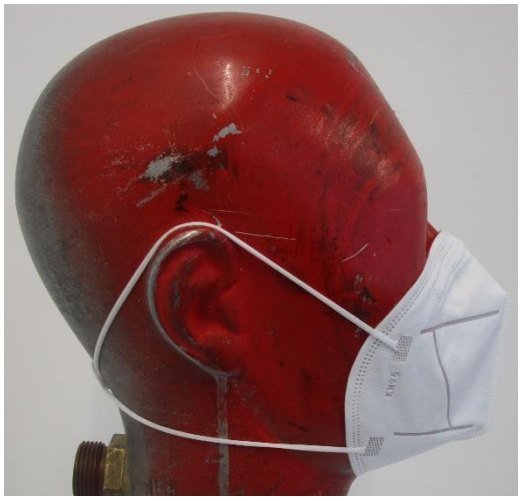
Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
AA1	125	144	130	47	581	Male
CB1	117	147	130	57	566	Male
RS1	109	141	120	50	545	Female
SI1	121	135	142	48	575	Male
JA1	117	134	129	49	565	Male
JS2	126	142	125	57	575	Male
MN1	115	137	142	60	585	Male

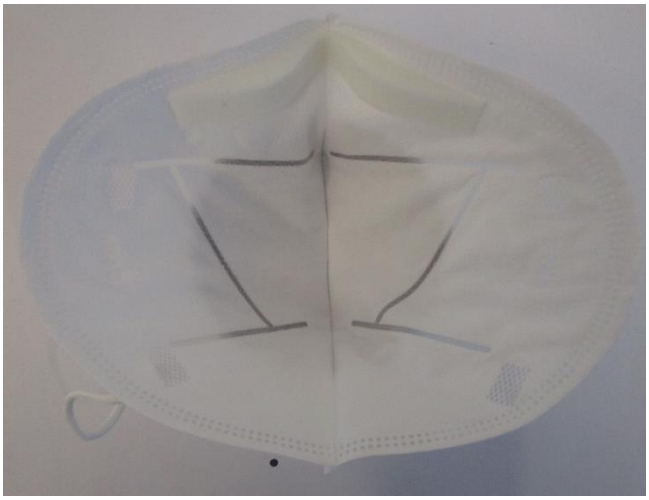
Note: All candidates were clean shaven

Product photographs.

Front view



Side view



Inside view

End of Report

Section 7

Draft EU Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer and address	Medical Devices Technology International Ltd, The Kace Building, Victoria Passage, Wolverhampton WV1 4LG, West Midlands, United Kingdom
Product name	KN95 (NR)/FFP2 Particulate Respirator
Model/ Serial No.	KN95
Technical Reference:	BSI's PPE for Healthcare Professionals 2020/403 -Respiratory Protective Equipment Technical Specification
Applicable Regulation:	PPE Regulation 2016/425
Notified body for EU type-examination (Module B)	BSI Group – NB2797 BSI Group, The Netherlands B.V. Postbus 74103 1070 BC AMSTERDAM Nederland
Certificate number	CE 730967
Notified body for EU type-examination (Module C2)	BSI Group - NB2797 BSI Group, The Netherlands B.V. Postbus 74103 1070 BC AMSTERDAM Nederland
CE Marking Dimensions	CE 1.12cm x1.43cm

We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

Signed for and on behalf of: Medical Devices Technology International Ltd
(Date of signature): 09/09/2020
(Title of signatory): Chief Executive Officer
(Name of signatory): Prof Martin Levermore MBE DL
(Signature): Mlevermore

Section 8

Product Marking

All product packaging shall be printed with the following information.

CE 2797	Mandatory conformity marking. CE mark followed by Notified Body Number, which is involved in the control procedure for the final product according to Module C2 of the PPE Regulation (EU) 2016/425
MYAID	Manufacturer's logo
MODEL KN95/FFP2	Model Name
EAN 5060228630330	Unique Mask reference
NR	Non-reuse
	Single use symbol – do not reuse
CE	CE Marking dimension 1.12cm x1.43cm
LOT 2020.XA	Production Lot/Batch number

Product marking shall be printed with the following information:

MYAID EAN 5060228630330	Manufacturer logo and Product Unique ID
CE 2797	Notified Body CE mark number
KN95 FFP2 NR	Model Number and Classification

Section 9

User Instructions

INFORMATION FOR USERS

Product: MODEL KN95(NR) /FFP2 PARTICULATE RESPIRATOR
Model No.: KN95

Manufacturer: Medical Devices Technology International Ltd, The Kace Building, Victoria Passage, Wolverhampton WV1 4LG, West Midlands United Kingdom.

CE Approvals: The product meets the requirements of the European PPE Regulation (EU) 2016/425 and carry the CE mark and BSI's PPE for Healthcare Professionals 2020/43 – Respiratory Protective Equipment Technical Specification. Certification under Module B CE 730967, EU Type-Examination and Module C2 CE 730969, EC Quality Control, has been issued by BSI Group, The Netherlands B.V. Postbus 74103 1070 BC AMSTERDAM Nederland (Notified Body Number 2797).

RISK THAT PPE IS DESIGN TO PROTECT: Designed to support the use of disposable respirators as part of the PPE ensemble worn by Healthcare Professionals for reduction of aerosol generating around patients**.**

WARNING:

This filtering half mask is manufactured for COVID-protection only. This filtering half mask is not a PPE device for general use and shall not be used for purposes other than protection of COVID-19.

This product is a single user disposable product, only used for respiratory protection of some particulate matter.

Fitting reference is shown below. If you cannot achieve proper fit, do not enter a contaminated area.

HOW TO USE A MASK

- Before wearing a mask, wash your hands with an alcohol-based disinfectant or with soap and warm water.
- Cover your mouth and nose with the mask and make sure the mask is firmly pressed against your face.
- Do not touch the mask while you are wearing it; if you do, wash your hands with an alcohol-based disinfectant or with soap and warm water afterward.
- Replace the mask as soon as it gets wet and do not reuse disposable masks.
- Remove the mask from behind (do not touch its front side); throw it away in a closed container and then wash your hands with an alcohol-based disinfectant or with soap and warm water.

Storage: Store masks in a dry, ventilated, and non-corrosive gas environment.
Ideal temperature: 0 - 50° C, relative humidity: below 50% RH, **Shelf Life:** 2 years

Section 10

DECLARATION STATEMENTS

The PPE Regulation requires declaration statements from the manufacturer (CE certificate holder) covering the below requirements.

Retention of technical documentation/records
Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market.

Design & manufacturing process changes
The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type- examination certificate of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.

Major complaints & product recall
Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

User Instruction languages
Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

Note: State that the UI will be issued in the language of the applicable EU country