

**POCKET SIZE PERSONAL RESPIRATORY PROTECTION HOOD –
SPECIFICATION**
(GENERAL, REQUIREMENTS & TESTING METHODS)

CHAPTER A – GENERAL

101. Specification

The following specification covers the requirement of personal safety protection factors for emergency use by typically untrained persons in a hazardous or IDLH (*Immediate Danger to Life or Health*) situation. The concept of IDLH situations should include the expected, known or suspected presence of hazardous substances in the atmosphere. Hazardous substances are those which could affect the respiratory and ocular function and result in chronic or acute symptoms and or impede the normally urgent safe journey to safety. Hazardous substances may include, harmful particles such as microorganisms, smoke, fumes and aerosols, organic chemicals and poisonous gases. The protection should be suitably sized and small enough to be carried at all times without restriction or obstruction, (*pocket size*) and low weight. One product size should accommodate all persons of differing size, shape, ethnic and medical requirements of long hair, beards and spectacles hearing aids. The protection should be easy to don and doff quickly and visible external packaging instructions must accommodate all relevant information factors. Limitations of use must clearly be stated.

The packaging should take into account ethnic language requirements and either accommodate this by the use of pictograms or point towards a web or similar information centre.

The individual packaging should avoid hard or rigid containers which might prevent the packing into small pockets or handbags.

102. References

ISO Standard - #2859	134
European Standard EN ⁻	
European Standard EN ⁻	
European Standard EN ¹³⁶	-
European Standard EN ¹⁴⁰	-
European Standard EN ¹⁴³	
American Specification – September 30, 2003”	405 “NIOSH Statement of Standard for CBRN Respirator,

103. Definitions

Definitions to be applied to this Specification:

- 103.1 Product – Hood mask as per this specification
- 103.2 Mask – Hood mask as per this specification
- 103.3 Gases – Gases as indicated in Table 2
- 103.4 NIOSH Specification – American Specification – “NIOSH Statement of Standard for CBRN Respirator, September 30, 2003
- 103.5 Bite – Elastic apparatus that enters the mouth enabling breathing, similar to the mouthpiece of a diver.
- 103.6 CO₂ – Carbon Dioxide created in the lungs of the mask’s user.

- 103.7 Testing Batch – Masks from one and the same production and packaging batch.
- 103.8 Production Batch – Quantity of masks produced in one production run, from one and the same design and materials.

104. Classification

The masks are classified as follows:

- 104.1. **Type I** – Masks designed to filter particles and microorganisms for longer use.
 - 104.1.1 Masks in individual packaging.
 - 104.1.2 Masks in secondary packaging.
 - 104.1.3 Masks in detachable, portable wall cabinets.
- 104.2. **Type II** – Escape masks designed to filter particles, microorganisms, smoke, fumes and organic gases.
 - 104.2.1 Masks in individual packaging.
 - 104.2.2 Masks in secondary packaging.
 - 104.2.3 Masks in detachable, portable wall cabinets.
- 104.3. **Type III** – Escape masks designed to filter particles, microorganisms, smoke, fumes, organic and acid gases.
 - 104.3.1 Masks in individual packaging.
 - 104.3.2 Masks in secondary packaging.
 - 104.3.3 Masks in detachable, portable wall cabinets.

105. Packaging The masks will be packaged as follows:

- 105.1 Masks in individual packaging
- 105.2 Quantities of masks packed in cartons for storage
- 105.3 Quantities of masks packed in detachable portable wall cabinets

106. Labeling

- 106.1. Masks in individual packaging
 - 106.1.1. Mask definition: Hood mask according to Type
 - 106.1.2. Manufacturer's name and address
 - 106.1.3. When the Mask should be used
 - 106.1.4. Method of Use of Mask
 - 106.1.5. Instructions for donning the mask, including diagrams
 - 106.1.6. Various Warnings
 - 106.1.6.1. For **Type II** and **Type III**; Warning stating that the mask does not provide complete protection, - efficiency of filtering is dependent on the level of contaminants in the atmosphere; it is therefore important to leave the danger area as quickly as possible.
 - 106.1.6.2. Warning regarding accessibility to children
 - 106.1.6.3. Warning stating that the mask is not intended for use in the event of oxygen deficiency
 - 106.1.6.4. Warning against use of the mask by sick people or persons suffering from respiratory illnesses.
 - 106.1.6.5. Warning against use of the mask by children under the age of 8 years, who are unaccompanied by an adult.
 - 106.1.6.6. Warning against the effects of open flames on the mask
 - 106.1.7. Restrictions for use of the mask

- 106.1.8. Expiry date
- 106.1.9. Marking to identify production batch
- 106.2. Mask in Storage Carton
- 106.2.1. Name of Product
- 106.2.2. Quantity
- 106.2.3. Expiry date
- 106.2.4. Marking to identify production batch
- 106.2.5. Storage restrictions
- 106.2.6. Warnings
- 106.3. Masks in Cabinets
- 106.3.1. Name of Product
- 106.3.2. Quantity
- 106.3.3. Manufacturer's name and Address
- 106.3.4. Instructions for donning the Mask including diagrams
- 106.3.5. Warnings to Users
- 106.3.5.1. For **Type II** and **Type III**; Warning stating that the mask does not provide complete protection, - efficiency of filtering is dependent on the level of contaminants in the atmosphere; it is therefore important to leave the danger area as quickly as possible.
- 106.3.5.2. Warning regarding accessibility to children
- 106.3.5.3. Warning stating that the mask is not intended for use in the event of oxygen deficiency
- 106.3.5.4. Warning against use of the mask by sick people or persons suffering from respiratory illnesses.
- 106.3.5.5. Warning against use of the mask by children under the age of 8 years, who are unaccompanied by an adult.
- 106.3.5.6. Warning against the effects of open flames on the mask.
- 106.3.6. Restrictions to Users
- 106.3.7. Expiry Date
- 106.3.8. Marking to identify production batch

- 107. **Compliance to Specification.**
- 107. 1. 1. Compliance of masks to specification is based on ISO Standard # 2859.
Testing according to AQL 2.5 Testing Level S-3.
- 107.1.2. Size of the sampling will be determined according to Table 1, and quantity of masks will be taken for testing at random, from different packaging.
- 107. 1.3. quantities of masks required for testing in the testing method are indicated in this specification, the sampling chosen will be taken from "size of sampling" and the results will reflect the decision to confirm or reject.
If the quantity in "size of sampling" is insufficient, an additional random quantity of masks may be taken.
Singular Test Plan for regular testing.
Compliance of One Mask to Specification – In order to determine whether one mask complies with the specification, all aspects of the specification must be tested. The mask complies with the specification if all the requirements are met. The mask does not comply with the specification if the requirements or part thereof, are not met (in terms of 107.1. above).
- 107.1.4.
- 107.2.

TABLE 1
AQL – 2.5 Test Level S-3

Quantity in Sample		Level Code	Sample size	Decision	
From-	To-			Approved	Disqualified
281	500	D	8	0	1
501	3,200	E	13	1	2
3,201	35,000	F	20	1	2
35,001	500,000	G	32	2	3
500,001	UP	H	50	3	4

107.3. The parties, in agreement, are entitled to determine different quantities and testing percentages pertaining to all characteristics as they appear in the Table according to 107.1

APTER B – GENERAL REQUIREMENTS

201 The mask seal test by avoiding penetration of air between the face and the mask while the inhalation filter is blocked will give the following protective factors:

201.1. Protective factor of 1:250 to 90% of users

201.2. The above tests will be conducted with air flow rate of 30 liters per minute.

202 Filtration capabilities

202.1 Smoke and fumes for **Type II** and **Type III** masks.

202.1.1 When tested according to ISO 12103-1 Standard Coarse Grade Test Dust, for 15 minutes with airflow of 10 cub. Ft. per minute containing 16.0 gr. of dust, at least 90% will be absorbed into the filter layer.

202.2 Gas Filtering Capabilities for **Type III**

202.2.1 The gas filtering capabilities according to Table 2 will be conducted with air flow rate of 30 liters per minute

202.2.2 The minimum breakthrough time is intended only for laboratory tests under standardized conditions. It does not give an indication of the possible service time in practical use. Possible service time may differ from the breakthrough times determined according to this standard in both directions positive or negative depending on the conditions of use.

TABLE 2

Test Agent	Concentration in air (PPM)	Breakthrough concentration (PPM)	Minimum Breakthrough time
Organic Phosphorous Gases	200	20	10
Chlorine Cl ₂	25	5	10
Hydrogen Sulfide H ₂ S	300	50	10
Hydrogen Cyanide HCN	250	30	10
Sulfur Dioxide SO ₂	100	25	10

203 Filtering Efficiency Particles

When testing the filtering efficiency to aerosol particles with NaCl at an air flow rate of 30 liters per minute, the amount of particles should not exceed more than 1 %.(P-3)

204 Breathing Resistance should be as follows:

204.1.1 Resistance to inhalation of **Type I** and **Type II** should not exceed 30 mm water at air flow rate of 30 liters per minute

204.1.2 Resistance to inhalation of **Type III** mask should not exceed 100 mm water at air flow rate of 30 liters per minute

204.2 Resistance to exhalation should not exceed 10 mm water at air flow rate of 30 liters per minute

204.1. Resistance to inhalation at air flow rate of 42 liters per minute for **Type II** and **Type III**, should not exceed 150 mm water

205 Accumulation of Carbon Dioxide (CO₂)

205.1 There is no requirement for testing Accumulations of Carbon Dioxide for the first 10 minutes of use.

205.2 When use exceeds 10 minutes, accumulation of Carbon Dioxide should not exceed 3% above the average concentration of the subject when tested without the mask. Each test should be lengthened by an additional 10 minutes over and above the requirement in 205.1. The CO₂ data recorded for the last 5 minutes will take into account the last 5 breaths, that will be mathematically compared to the CO₂ accumulation found on the subject tested prior to use of the mask.

206 Heat burden - Wearing the mask for duration of 10 minutes will not cause extreme heat discomfort that could result in its removal.

207 Skin Irritation - Wearing the mask for duration of 30 minutes will not irritate the skin. The inner material that comes into contact with the skin must be inert to the skin.

208 Preventing the growth of Microorganisms inside the filter - The mask must have the capability to prevent the development of Microorganisms inside the filter near the mouth, when the mask is worn beyond the stated time use.

209 The mask must fit wearers **with long hair, spectacles, beards and moustaches.**

210 Measurements - One size will fit 90% of the population over the age of 6 years, from 5% of the lower level, up to 95% of the higher level.

211 Donning and Removal – Unpracticed populations will be able to don, wear and remove the mask. 20 Seconds are required to perform actions 210.1. to 210.3 as follows:

211. 1 Removal of the mask from packaging

211. 2 Donning the mask

211. 3 Fastening the protective apparatus

211. 4 Minimal protection will be achieved by tightening the first fastening apparatus – additional fastening can be performed following the first tightening.

211. 5 Pressure from the mask will not cause pain to the head or neck. 211. 6 The mask will not hamper movements of the head in all directions. 211. 7 The mask will not loosen unintentionally.

211. 8 The wearer will be able to remove the mask unaided in a simple manner for 90% of users over the age of 6 years, from 5% on the lower level up to 95% on the higher level.

212 Communication –

212.1 Frontal communication – the mask will not hamper quality of visibility more than 90%.

212.2 The requirement is for movement of the head sideways and upwards and downwards.

212.3 Verbal communication – speaking and hearing –for a distance of 2 meters between two users.

212.4 The use of cellular telephone is possible whilst wearing the mask.

213 **Maximum Weight** of the mask in its first level packaging should not exceed 100 grams.

214 **First Level Packaging**

214.1 First level packaging –

214.1.1 Vacuum pack, avoiding hard or rigid containers that might prevent the packing into small pockets or handbags, easy-open, no cutting or piercing device required. Vacuum pack shall not contain any holes, rips, tears, cuts, or open seams. When tested for leakage test, pack should not leak.

214.1.2 Length: 12±3 cm. 12±3 cm.

214.2 Width: up to 2 cm. for **Type I** and **Type II.** up to

214.2.1 First level Measurements:

214.2.2 Thickness: 3 cm. for **Type III.**

214.2.3.1 Thickness:

214.2.3.2

Table 3;

Features, Requirements paragraphs and test paragraphs for each Type.

Requirement	Type I		Type II		Type III	
Time of intended use	Up to 3 hours		15 minutes*		10 minutes*	
	# Requirement	# Test	# Requirement	# Test	# Requirement	# Test
Protective Factor	201	301	201	301	201	301
Filtration: Smoke	---	---	202.1*	302.1	202.1*	302.1
Filtration: Gases	---	---	--- **	---**	202.2*	302.2
Filtration: Particles & Microorganism	203	303	203	303	203	303
Breathing resistance	204.1.1	304	204.1.1	304	204.1.2	304
Accumulation CO ₂	205	305	205	305	205	305
Heat Burden	206	306	206	306	206	306
Skin irritation	207	307	207	307	207	307
Preventing the growth of Microorganisms	208 ***	308 ***	208 ***	308 ***	208 ***	308 ***
Fit spectacles, long hair and beards	209	309	209	309	209	309
One size fits all	210	310	210	310	210	310
Donning time within 20 seconds	211	311	211	311	211	311
Vision & Communication	212	312	212	312	212	312
Weight not to exceed 100 gr.	213	313	213	313	213	313
Package Size	214 L 12±3cm W 12±3cm T 2 cm	314	214 L 12±3cm W 12±3cm T 2 cm	314	214 L 12±3cm W 12±3cm T 3 cm	314

* The protection factors and filter breakthrough data in particular was developed from laboratory tests under supervised use and standardized conditions. These protection factors may vary in practical use due to hazard concentration or dilution factors and therefore should be used as a guide as only. The minimum breakthrough time is intended only for laboratory tests under standardized conditions. It does not give an indication of the possible service time in practical use. Possible service times can differ from the breakthrough times determined according to this standard in both directions positive or negative depending on the conditions of use.

** Although there is no specification for gas defense measurement in the **Type II** filter, its layer of activated charcoal is capable of the adsorption of limited quantities of the following gases; Cyclohexane, Hydrogen Cyanide, Phosgene, and Chlorine often present in emergency evacuation and smoke.

*** The filtration system protects against the breakthrough of external challenge microorganisms but the inner filter layer has been treated with an antimicrobial to prevent the build up of exhaled natural flora, usually associated with long term use of any respiratory protection and often results in sore throats.

CHAPTER C – TESTING METHODS

(Unless otherwise stated, the quantity for testing is according to Table 1)

301 Testing of Protection Factor

(This test includes also the requirements set out in paragraphs 208 and 209)

- 301.1. Number of participants (some of which are tested and conform to requirements set out in paragraph 208) Number of samples for the test, and preparation for test according to EN 405).
- 301.2. The protection factor of the mask (not including the inhalation filter) can be tested in one of the following systems:
- 301.2.1 Testing material NaCl according to EN 140 – 2.4.5. The mask is tested as follows:
Inhalation filters of the mask are securely replaced by an elastic tube of minimum 10mm inner diameter, the other end of the tube is placed outside of the testing chamber with a filter connected to this tube end. There should be no air penetration between the mask and the filter. While the examinee remains in the testing chamber, and the filter is outside of the testing chamber, proceed with the tests as per EN 140 – 2.4.5.
- 301.2.2 Inhalation filters of the mask are replaced by an elastic tube of minimum 10 mm inner diameter. The other end of the tube is connected to a T connection. A cock is connected to one of the T connections, and a vacuum meter between 0 to 76 cm of mercury is connected to the other T connection. The examinee, with the properly donned mask as described above, walks on a conveyor (Treadmill) at the speed of 5.5 km/hour. The sector cock is closed. When maximum vacuum is reached for this particular examinee, he holds his breath for 30 seconds while walking and moving his head to both sides, and upwards and downwards. No entrance of air into the space between the mask and examinee face is permitted. The vacuum meter should show the same vacuum for the entire 30 seconds.
- 301.3. Test results should not deviate from requirements in paragraphs 201.1 and 201.2.

302

302.1

Filtering Capability: – the test will be conducted on 2 masks. Smoke

Filtering Capability:

Tested according to ISO 12103-1 Standard Coarse Grade Test Dust, for 15 minutes with airflow of 10 cub. Ft. per minute containing 16.0 gr. of dust, at least 90% will be absorbed into the filter layer.

302.2

302.2.1

Gas Filtering Capability

The mask will be fitted onto a stainless steel or non absorbent plastic dummy. The dummy should be made in such a manner as to avoid the entry of air except via the filter. The part intended to fit around the neck is fastened with gas resistant adhesive tape. At the front there will be an opening (like the mouth) attached to a vacuum pump with a capacity of 30 ± 2 liters per minute. The other end of the pump will be attached to a chamber that facilitates the collection of gases. The dummy head, fitted with the mask, will be placed into a sealed hollow chamber into which the testing gas can flow.

- 302.2.2 Relative humidity outside the testing chamber will be $60 \pm 15\%$ at a temperature of 20 ± 2 o C.
- 302.2.3 The hollow testing chamber will be connected to an exterior container filled with pure nitrogen together with the concentration of gas indicated in the Table 201.1 – the concentration entering the chamber to be within the limits of $\pm 10\%$ of the value stipulated in Table 2.
- 302.2.4 Duration of the test is 10 minutes.
- 302.2.4 Any acceptable trial method may be used to obtain the stipulated concentration at the end of the pump, under conditions where the resulting concentration is $\pm 20\%$ of the breakthrough value stipulated in the Table.
- 302.2.5 Breakthrough time recorded will be collated, if necessary, by simple relativity, to the stipulated value of the gas in the nitrogen.
303. **Testing of Filtration efficiency** – to be conducted on 2 masks.
- 303.1 Mask to be fitted to a stainless steel or gas resistant dummy head. The dummy should be made in such a manner as to avoid the entry of air except via the filter. The part intended to fit around the neck is fastened with gas resistant adhesive tape. At the front there will be an opening (like the mouth) attached to a vacuum pump with a capacity of 30 ± 0.5 liters per minute. The other end of the pump will be attached to a chamber that facilitates the collection of gases. The dummy head, fitted with the mask, will be placed into a sealed hollow chamber into which the testing aerosol can flow.
- 303.2 Test according to EN-143 NaCl aerosol.
- 303.3 The quantity in the collection chamber will be divided by the quantity in the delivery chamber, multiplied by 100 which will result in the percentage unfiltered.
304. **Testing of Breathing and Exhalation Resistance** – To be conducted on one mask per test.
- Mask to be fitted to a stainless steel or gas resistant dummy head. The dummy should be made in such a manner as to avoid the entry of air except via the filter. The part intended to fit around the neck is fastened with gas resistant adhesive tape. At the front there will be an opening (like the mouth) attached to a vacuum pump with a variable capacity of 30 to 48 liters per minute. A transparent PVC tube will be sealed securely into the mask, with the other end of the tube to be attached to a “U” shaped glass tube marked in millimeters, on both sides from -200 mm up to +200 mm, the U tube is filled with colored water leveled on both sides on the 0 mark between the + and – numbers.
- Activation of the pump will be with intake of vacuum of 30 liters per minute. The colored water level will not rise above the measuring mark of -30mm for **Type I** and **Type II** masks, and will not rise above -100mm for **Type III** mask.
- 304.1 Direction of the pump will be changed when air is pumped into the hollow between the mask and the dummy. The water in the “U” tube will not deviate from +10mm above the water level of 0.
- 304.2 The pump will be activated with intake of vacuum of 48 liters per minute. The water level will not go above the measuring mark of 150 mm.

305. Test for Accumulation of CO₂

- 305.1 It is not necessary to check accumulation of CO₂ for the first 10 minutes.
 305.2 The test will be conducted as follows:- 6 users in standing position, 6 users whilst walking.

305.3 Test Procedure:

- 1.1. Testing of concentrations of CO₂ after 10 minutes of wearing the mask.
 1.2. NIOSH Specification paragraph 3.4.2 requires testing of CO₂ concentrations in positions of rest and effort and this specification defines the means, method, and required results.
2. Means
- 2.1. The test will be conducted by means of a CO₂ _{detector}, at detection sensitization limits of 0 – 10% for CO₂.
 2.2. The reading will be taken from an optic display, at accuracy of 2 digits after the decimal point.
 2.3. The accumulation will be taken from a data collector at readings of accumulation of 15 seconds.
 2.4. The air pump between the open space (hollow) in the mask against the cheek near the mouth will supply air at a flow of 0.1 to 0.2 liters per minute, into the sensitizer of the detector.
 2.5. PVC tube between the open space in the mask through the pump to the sensitizer
 2.6. A disposable tube connector unit to test CO₂ inside the mouth prior to donning the mask.
 2.7. Treadmill with speed of 5.5 K.M.H
 2.8. Stop Watch
 2.9. Equipment listed in 2.1 to 2.4 to be calibrated before use.
2. Examinee tested
- 3.1. Minimum age of examinee is 18 years.
 3.2. Examinees suffering from respiratory, lung or other ailments will not be eligible for testing.
 For each examinee, the following data must be recorded:
- 3.3. Date of Test
- 3.3.1 Name, (at least first name) and sex
 3.3.2 Age
 3.3.3 Height
 3.3.4 Position of examinee during the test, whether in standing position, or whilst walking
 3.3.5
4. Method
- 4.1 Tests to be conducted in two ways:
- 4.1.1. Standing Test
 4.1.1.1. Whilst walking on a Treadmill at speed of 3.5 miles per hour
 4.1.1.2. (approximately 5.5. k.p.h)
- 4.2 Test will be conducted according to paragraph 2 as above.
 4.3 Method of Donning the mask; correct breathing, and use of the mask will be explained to the examinee.

- 4.4 Use of apparatus in the examination room. Reading inside the room should not exceed 0.09%. The reading should reach below the accepted level of 0.09% before commencing the test. If the reading exceeds the accepted level, it is forbidden to conduct the tests.
- 4.5 Checking of exhaled air of the examinee prior to the test. The percentage level of natural exhalation of CO₂ of the examinee must be tested prior to donning of the mask. The result will be used to calculate the accepted quantity allowed.
- 4.5.1 After activation of the pump, attach the disposable tube connector. Insert the disposable tube connector into the mouth of the examinee.
- 4.5.2 Continue the procedure for at least 120 seconds.
- 4.5.3 The average readings for the last 30 seconds (two readings before removal of the disposable connector) are the normal average CO₂ exhaled levels of the examinee.
- 4.6 Test Procedure
- 4.6.1. The examinee will don the mask in the method described in 106.1.4. If the mask is a hood type, the mask should be donned in a way to ensure that all sides of the mask are stretched to their limit.
If there are elastic fasteners around the neck, the sides beneath the elastic fastener/s should be stretched to ensure minimum space between the head and the mask.
- 4.6.1.1. If the mask has a mouthpiece, it must be inside the mouth in the manner described in 106.1.4; if there is no mouthpiece, the one way exhalation valve should be placed opposite the lips.
- 4.6.1.2. For hood type masks without a mouthpiece, it should be explained to the examinee that during use of the mask, the one-way exhalation filter must be placed opposite the mouth, in contact with the lips, and exhalation of air should be into the one-way filter. Exhaled air should be exhaled into the one way filter.
- 4.7. The exposed end of the PVC tube will be inserted via the neck with its edge against the right cheek at a height of 1 cm to 3 cm above the mouth level. The tube within the mask must be straight, without kinks.
- 4.8. Duration of the test is 20 minutes. Results obtained in the test will be stored in the data collector as described in 2.3. above.
- 4.9. For each test, the recorded data will be for the last 5 minutes. For those last 5 minutes, the results of the last 5 readings will be recorded as the result. For clarification, the last 5 readings are the readings at the time of collection of data while the tube remains in the mask (see par # 5.6).
- 4.10. The examinees described in par # 4.1. need not necessarily be the same. Different examinees for standing and for walking can be used.
- 4.11. Each group should consist of at least 12 examinees.
5. Records, Results and Documentation.
- 5.1. The data collected will be converted to a graphic display, (preferably Excel file)
- 5.2. The graph will reflect correlation between time of reading and the data obtained.
- 5.3. The data will be displayed with the X representing time, and Y representing CO₂ %.
- 5.4. The accepted graph will include the data appearing in par # 3.3.

- 5.5. The graph marked in correlation to X will be:
- 5.5.1. The actual reading.
- 5.5.2. The calculated data which is the difference between the actual readings less the average CO₂ exhalation, as described in par #. 4.5.3
- 5.6. Interpretation of Results:
- 5.6.1 The last 5 results of the data in par #. 5.5.2 are the results of calculated percentage of CO₂ for that examinee. After deduction of the result in par #. 4.5.3 of the same examinee, the upper border level for this reading should not exceed 3% CO₂.
- 5.6.2 The graph in par #. 5.5.1 should show an average tendency downwards. An average of wearing the mask for 10 minutes in the range of the second 10 minutes, reveals that there is no accumulation of CO₂ inside the mask in the second 10 minutes.
- 5.6.3. Non conformance to one of the two above conditions reveals a failure of the test.
If 90% of the accumulated results in paragraphs #. 5.6.1 – 5.6.2 are satisfactory, the mask is acceptable.
- 306. Heat Resistance Test**
The test will be conducted on different examinees of varying ages from 18 to 48 years, varying in weight and height; on a treadmill at a speed of 5.5 k.p.h. Required outside temperature is 20 ± 2 °C ; and relative humidity should be 50 ± 20 % . Examinees will wear the mask for duration of 10 minutes, without feeling unbearable heat build up that could force them to remove the mask.
- 307. Skin Irritation Test**
The inner surface of the mask should be made from proven non-irritant material. Material referenced in European or American Pharmacopoeia is sufficient. Manufacturer's testing on the material is acceptable.
- 308. Evaluation of preventing the growth of Microorganisms on the inside of the filter.**
Prepare 0.1 ml of an 8 hour broth culture (Tryptone Soya Broth) of 2 out of the following microorganism species; Bacillus subtilis, Staphylococcus aureus, Pseudomonas fluorescens, Escherichia coli, Salmonella enteritidis, Serratia marcescens, Proteus mirabilis, Bacillus subtilis spores. Spread the selected microorganisms on the surface of Tryptone Soya Agar Petri plate using glass spreaders.
Place a drop of the agar on the surface of the selected layer, intended to face the mouth of the intended user, and incubate for 24 hours at 36 ± 1 °C.
Evaluate the growth of the inhibition haloes.
The growth of the two selected microorganism should not exceed **4mm**.
- 309. Compatibility Test for Wearers with long hair/Spectacles; Beards/Moustaches**
Test according to par #. 301.1 of this specification will include examinees described in the heading of this paragraph. Requirements in par #. 201

of the specification will be adapted to persons described in this paragraph.

310 Test to confirm One Size Fits 90% of the population over 6 years, from 5% on the lower level up to 95% on the higher level.

Test to be conducted according to par #. 301.1 – 90% of the examinees should conform.

311. Donning and Removal Test

311.1 Each examinee to carefully read the instructions label and confirm his/her understanding thereof. Long hair if relevant, to be gathered in an acceptable manner such as before donning hat. Time for hair gathering not to be included in the time frame stipulated in par #, 210.1 to 210.3. By means of stop watch, donning time to be measured as described in par #. 210.1 to 210.3. Required donning time per examinee should not exceed 20 seconds.

311.2 Masks are tested under conditions similar to regular usage conditions, as laid out in par #. 210.5 to 210.8

312 Vision and Communication Test

312.1 The Examinee with 6:6 vision, or who by means of spectacles reaches 6:6 vision; dons the mask in the acceptable manner as set out in the diagrams. After 4 minutes of wearing the mask, examinee's vision to be checked by showing him/her a sign written in letters of 150 mm height, from a distance of 6 meters.

312.2 After wearing of the mask for at least one minute, verbal communication between two examinees at a distance of 2 minutes from one another is checked. One examinee to repeat the words spoken by the other.

312.3 After four minutes of wearing the mask in the accepted manner as set out in the diagrams, the examinee uses a cellular telephone, hears, speaks and dials numbers without interference from the mask.

313 Weight Test

The packaged mask, including mask & packaging not to exceed 100 grams.

314 314.

1.1 First level Packaging Test

Hard or rigid shaped containers which might prevent the packing into small pockets or handbags are not acceptable.

314.1.2 **Easy open** – Open with fingers only, all way through, within 3

314.1.3 seconds.

Leakage test – Samples shall be conditioned at room temperature for 4 hours. Samples shall be submerged in water at least 80C above room temperature. Samples shall be held submerged in transparent vacuum chamber covered with a net wire cloth having weight of at least 200gr. Uppermost surface covered by not less than 2,5 cm of water. Vacuum

of 12 inches (30.5 cm.) Hg is created for at least 30 seconds. No leaking air bubbles should be visible.

314.2 Mask measurements to be checked to conform to the following limits: Length: 12 ± 3 cm (distance between thick parts along the length of the pack that exceed 3 mm)*

Width: 12 ± 3 cm (distance between thick parts along the width of the pack that exceed 3 mm)*

Thickness: not to exceed 2 cm at the thickest part for **Type I** and **Type II** and not to exceed 3 cm at the thickest part for **Type III**.

- * Whilst parts of the packaging that do not contain the mask contribute to the quality of the packaging, they are not included in the limits of measurements if they do not exceed 3 mm thickness, and it is possible to fold them without causing damage to the quality of the package.