

Documentation No.	:	novita-R5D
Creation Date	:	20202210
Revision No.	:	1
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Instruction Manual

I. Basic Information:

1. Product Name: Filtering Half Mask
2. Model / Size: novita R5 / 156mm x 110mm
3. Executive Standard: **RFU PPE-R/02.075 Version 1.**
4. Class: FFP2

Classification		FFP1	FFP2	FFP3
Requirements (Maximum)				
At least 46 out of the 50 individual exercise results for total inward leakage shall be not greater than.		25%	11%	5%
At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than.		22%	8%	2%
Max. Penetration of filter material. (Sodium chloride test 95 l/min & Paraffin oil test 95 l/min).		20%	6%	1%
Maximum permitted resistance (mbar)	Inhalation (30 l/min)	0,6	0,7	1,0
	Inhalation (95 l/min)	2,1	2,4	3,0
	Exhalation (160 l/min)	3,0	3,0	3,0

NR(Not reusable): It is non reusable, single shift use only



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5. Main Material:

- Layer 1 - Non-woven fabric (27%)
- Layer 2 – Melt blown non-woven (12%)
- Layer 3 – Melt blown non-woven (12%)
- Layer 4 – Hot Cotton (22%)
- Layer 5 – Non woven fabric (15%)
- Head Band – Polyester + spandex (10%)
- Nose bridge – Aluminum (2%)

6. Validity Period: 5 years

7. Production date: Please see production date on packaging box or bags.

8. Packaging: Respirators are packed in single bag, 8 pcs bag or 12 pcs bag.

II. Scope of Use and Purpose:

1. Scope of application: Filtering half mask to protect against particles.
2. Purpose: Respiratory protection of particulate filter
3. This filtering half mask is manufactured for COVID-19 protection only. As requested by World Health Organization recommendations, for this specific use, the nominal protection factor given by this filtering half mask is the same than the FFP2 nominal protection factor defined in EN 149:2001+A1:2009. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.”
4. This product is certified by CCQS Certification Services Limited

CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown,

Dublin 15, D15 AKK1, Ireland

Notified Body: 2834

III. Product Features:

1. The belt of the mask should be strong enough to fix the position of the mask. The breaking strength of each belt and the connection point of the mask should not be less than 10N
2. The bacterial filtration of the mask should be no less than 94%.
3. Ventilation resistance shall not be greater than 49 Pa/cm³

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IV. Product performance, structure and Composition:

This product is composed of mask body, nose clip and mask band, among which the mask body is composed of five layers of filtration materials. Two layers of polypropylene spunbonded non-woven cloth, two layers of polypropylene melt-sprayed non-woven cloth and one layer of hot air cotton.

The nose bridge is made of aluminum and the mask band is made from elastic nylon spandex.

This is a non-sterilization product and is disposable.

V. Restrictions of this Product

1. Warning - this product is not flame resistant and must not be used in areas with open flames
2. Do not alter, wash, abuse or misuse this product.
3. This product cannot produce oxygen and cannot be used in anoxic environment.
4. Do not use this product when facial whiskers, hair or other conditions can affect the closeness between the face and the mask.
5. The best continuous usage time of this product is 4 hours.
6. This product is designed for occupational/professional use for adults who are properly trained in its usage and limitation. This product is not designed to be used by children.
7. Individual with a compromised respiratory system, such as asthma or emphysema, should consult a physician and must complete a medical evaluation prior to use.
8. Storage and transportation: Before use, store respirators in the original packaging away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals. When stored in accordance with temperature and humidity conditions specified below, the product may be used until the "use by" date specified on packaging. Always inspect product and conduct a user seal check before use as specified in the User Instructions.

VI. Instructions for Use:

1. Wash your hands thoroughly with soap and water to perform hand hygiene before putting on the respirator.
2. Unfold the respirator. Flatten the metal nose bridge then bend it into a contour.
3. Hold the respirator by the ear loops.
4. Place a loop around each ear.
5. Position the respirator under your chin with the nose bridge up.
6. Using both hands, bend the metal nose bridge to fit snugly against your nose and face.
7. Perform a fit check. Place both hands completely over the respirator. Exhale sharply to check for air leaks.

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VII. Warning!

- **This product is not flame resistant and must not be used in areas with open flames**
- Before use, please read the User Instructions. If you have pre-existing lung disease such as asthma or emphysema, underlying heart disease such as heart failure or other health conditions, you may have difficulty breathing through some respirators and should consult your healthcare provider (doctor) before use.
- Although respirators can help reduce the number of particles you breathe, they will not eliminate the risk of symptoms or sickness.
- Wash your hands thoroughly with soap and water, or use Anti-Bac Spray/Hand Sanitizer, before handling the respirator.
- Inspect respirator for holes, tears or other damage to surfaces, straps, metal nose bridge and nose bridge pad. If your respirator has been damaged – DO NOT USE IT. Get a new one.
- Go to a clean, safe area, and replace your respirator if it is damaged, soiled or breathing becomes difficult, leave the contaminated area immediately and replace the respirator.

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- Always do a fit check when you wear the respirator. Completely cover the outside of the respirator with both hands. Do not push the respirator against your face. With your hands in place on the surface of the respirator, exhale, or breathe out sharply. If you feel air blowing on your face or eyes, the respirator needs to be adjusted. When respirator is a good fit, you will not feel any air blowing on your face or eyes.
- It is unlikely that the requirement for leakage will be achieved if facial hair passes under the face seal
- If you wear glasses, please remove glasses before putting on the respirator. Return glasses to face, if applicable.
- Anything that comes between the respirator and your face will make the respirator less effective by interfering with its fit and leakage requirement; Hair, jewellery and clothing should not be between your face and the respirator.
- Do not alter, abuse or use this respirator other than as stated.
 - You should never wash, reuse or share your respirator with others.
 - Do not use respirators for gases and vapours, areas with low oxygen levels, asbestos, lead, large areas of mold and other hazardous substances such as explosive atmosphere.
- The information shall provide recommendation as to when the particle filtering half mask shall be discarded
- For devices marked “NR”, a warning shall be given that the particle filtering half mask shall not be used for more than one shift.

VIII. Storage Method:

1. Pay attention to waterproof, high temperature, moisture and corrosion resistant gas.
2. Store in a dry, ventilated and non-corrosive environment, away from ignition sources and inflammables.
3. Storage Temperature: -20 °C to 40°C
4. Storage Humidity: <80%
5. The respirator may be used until the expiry date specified on packaging.
6. Always inspect product and conduct a user seal check before use as specified in the Wearing Instructions.

X. Special figures and meanings



See information supplied by the manufacturer



Scan here to view Annex 1X Doc

MADE IN SINGAPORE

Manufacturer Name: novita, 9 Koi Marketing Pte Ltd

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Notes:

All the information in the instruction will be at least in the official language(s) of the destination country when the product be put into the market.