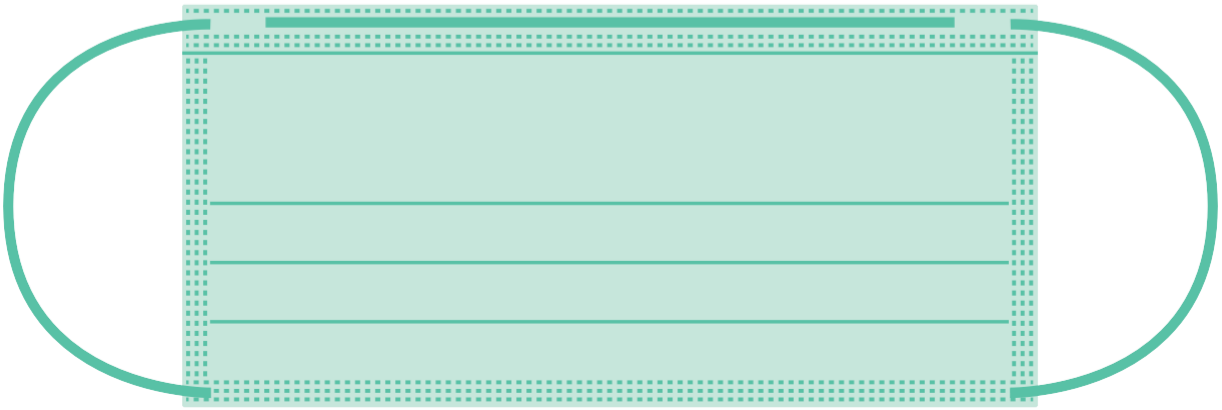
ANTIVIRAL
TYPE IIR MASK

INSTRUCTIONS FOR USE

protect™



Version 1.3 – April 2021

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DONNING THE MASK

1.
Thoroughly wash and dry your hands.

2.
Remove the mask from its packaging. Hold the mask with the outer layer out. The outer layer will be facing up and is coloured green. This layer should be away from your face when donned.

3.
With the pleats folding down, grasp the top of the mask at the center of the metal nose piece. Pull the bottom edge of the mask to open the pleats.

4.
Place the mask against your face with the nose piece centered on the bridge of your nose. Press the nose piece to the bridge of your nose and along your cheekbones to shape the mask to your face.

5.
Pull the ear loops over your ears.

6.
Press the nose piece to your face one more time to ensure a secure fit.

HOW DO I KNOW MY MASK IS ON CORRECTLY?

- The metal nose piece is at the top
- The pleats typically fall downwards and away from the nose (a “waterfall” pleat*)
- The white, or smoothest side, is on the inside against the wearer’s skin; the colour always faces out
- The wearer’s nose and mouth are covered by the face mask

SANITAS

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ANTIVIRAL TYPE IIR MASK
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REMOVING THE MASK

1.
Thoroughly wash and dry your hands.

2.
Release the mask by pulling the ear loops back over your ears. Avoid touching other parts of the mask to prevent contamination.

3.
Dispose in an appropriate waste container.

MASK DEFINITION

DESCRIPTION: All the features of our Type IIR mask, but with an additional outer layer featuring our patented technology demonstrated to kill human coronavirus 229E to greater than 99.9% in just 10 minutes (according to standard ISO 18184). Mask features soft and strong elastic ear loops and nose clip to ensure proper fit. The mask has a low respiratory resistance and a high bacterial filtration efficiency. It is intended to minimise cross contamination – the environment is protected against transmission and the wearer against spray or splashes at a pressure of 16 kPa.

SPECIFICATION: Dimensions: 176mm x 93mm | Ear loops 113mm | Cascade pleating | 5 layers

FEATURES: Type IIR approved according to EN 14683:2019 | Single use | Differential pressure of less than 60Pa/cm^2 Antiviral outer

PACKING: 50 units per box | 10 boxes per carton | 500 units per carton

STORAGE: Protect from light

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MASK STANDARDS & FREQUENTLY ASKED QUESTIONS

INDICATED USE

The Protect Antiviral Mask is a medical facemask primarily designed to act as a physical barrier to prevent transmission of pathogens from the wearer to the environment. It is tested according to the EN14683:2019 standard to confirm filtration performance and blood penetration resistance.

The Protect Mask consists of five pleated layers of non-woven fabric, bonded together. The four inner layers (from the wearer out) are formed from polypropylene. The outer cellulose layer is treated with our patented antimicrobial agent. The mask also features an aluminium nose strip and latex-free elastomeric ear loops to ensure a tight and comfortable fit.

No mask completely eliminates the risk of exposure to blood or bodily fluids.

DURATION OF WEAR

The duration of use of the Protect Antiviral Type IIR Mask may be very short – one medical procedure - or may be extended to several hours. Maximum intended duration of wear is 4 hours, as per WHO guidance.

MEDICAL FACE MASK STANDARDS AND REGULATIONS

The consensus standard for surgical style masks in the UK and Europe is EN14683:2019. The standard specifies performance requirements for medical face masks with four basic criteria:

BACTERIAL FILTRATION EFFICIENCY (BFE)

Measures a mask's ability to filter bacteria. EN14683:2019 specifies testing by aerosol with a droplet size of 3.0 microns containing Staphylococcus aureus. To be called a medical or surgical mask, a minimum 95% filtration rate is required. Moderate and high protection masks require bacterial filtration rates of greater than 98%. The Protect Antiviral Type IIR Mask returned performance of 99–99.9% BFE.

FLUID RESISTANCE

Reflects a mask's ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer of the mask as the result of a splash or spray. The Protect Antiviral Type IIR Mask has been tested to show fluid resistance at 16 kPa pressure.

DELTA P (PRESSURE DIFFERENTIAL)

Measures how light and breathable a mask feels. A controlled flow of air is driven through a mask and the pressure on either side of the mask is determined. The difference in pressure is measured and divided by the surface area (cm^2) of the mask segment tested. The higher the Delta P value, the more difficult it is for the wearer to breathe. The Delta P is measured in units of Pa/cm^2. The EN14683 standard requires that masks have a Delta P of less than 60, as a higher value would be considered too "hot" for general medical or surgical use. The Protect Antiviral Type IIR Mask has been found to have a delta P of < 30 Pa/cm^2.

BIOBURDEN

Facemasks must be tested to ensure they are not contaminated in the manufacturing process and are thus safe to use. The Protect Antiviral Type IIR Mask has been found to have < 10 cfu/g, vs the EN14683 requirement to be less than 30 cfu/g.

BIOCOMPATIBILITY (OR SKIN COMPATIBILITY)

In addition to the above tests, all face masks must be tested to an international standard (ISO 10993-5, 10) for skin sensitivity, irritation and cytotoxic tests to ensure no materials are harmful to the wearer. Tests are conducted on all materials used in construction of the mask, including the ties, elastic ear loops, and any piping materials used to hold the side pleats together. Our antimicrobial agent is bound to the fabric of the mask and cannot come off or leach. The successful Biocompatibility testing to international standard ISO10993 confirms the safety of the Protect Antiviral Type IIR Mask.

ANTIVIRAL AND ANTIBACTERIAL PERFORMANCE

The Protect Antiviral Type IIR Mask has been designed to inactivate pathogens that come in contact with the mask outer. It's performance has been independently testing according to recognized international standard test methods.

For example, on contamination with human coronavirus 229E (an accepted substitute for the COIVD-19 pathogen SARS-CoV-2) then a >99.9% reduction in virus was determined in just 10 minutes, according to method ISO18184.

In addition, the Protect has been tested for it's antibacterial performance to method AATCC 100, and shown excellent performance.

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FREQUENTLY ASKED QUESTIONS

WHAT IS THE PURPOSE OF A MEDICAL FACE MASK?

In the Operating Room (OR), surgical masks protect the sterile field from possible contamination, primarily as a result of coughing, sneezing or talking. A mask may also protect clinicians from the byproducts of surgical procedures such as bone chips, splashes of bodily fluids, and smoke plume resulting from laser or electrosurgical techniques.

Outside of the OR, masks are used for standard precautions to protect clinicians and patients from pathogens that may spread by blood or other bodily fluids, secretions or excretions. Surgical masks are effective protection against droplet transmission.

HOW LONG IS MY FACE MASK EFFECTIVE?

The filtration efficiency and protective ability of a face mask is compromised when the mask becomes soiled, wet, torn, or dislodged. Masks with higher protection values will generally maintain filtration for longer periods of time. However, it can also depend on humidity levels, respiration rate, nasal discharge, talking, etc. A mask should be worn for only one patient procedure or visit. If a mask gets wet or soiled, it should be replaced.

WHY IS THE FIT OF A MASK IMPORTANT?

A mask is only as effective as its fit. There should be no gaps along the side, around the nose or under the chin that would allow air and droplets to bypass the filter medium. The mask should always be properly adjusted to fully cover both the mouth and nose. A well-fitting mask stays in place over the nose and cheeks and even a standard mask will prevent fogging of eyeglasses if it fits properly. Masks should not be worn underneath the nose or dangling around the neck – they should either be fully donned or disposed of.

HOW DO I ENSURE A GOOD FIT?

There are several things that contribute to a good fit. The most important consideration is the nose piece. It should mold over the nose and cheeks and maintain its shape over time. It should not kink or break when adjusted. In the case of a mask with surgical ties, the upper ties should sit at the crown of the head, and the lower ties should be tied behind the neck to hold the sides of the mask against the face to prevent any gaping. Individuals with wider faces should select a mask that ensures full coverage over the face and under the chin.

WHAT IS THE DIFFERENCE BETWEEN A MEDICAL MASK AND A RESPIRATOR?

Medical masks (surgical/procedure masks) are loose fitting masks that cover the mouth and nose. They are designed to stop large droplets and splashes or sprays but are not designed to seal tightly to the face or filter small airborne contaminants.

A respirator is an item of personal protective equipment (PPE) designed to reduce exposure to airborne contaminants and pathogens. Respirators must be individually selected to fit the wearers face and shown to provide a good seal. They also must be certified by a Notified Body and used within a comprehensive respiratory program including fit testing and training.

WHAT ELSE SHOULD I KNOW ABOUT FACE MASKS?

All individuals using face masks must be aware of the protective capabilities of the mask being worn. Health care workers should assess their risk of exposure to blood, bodily fluids, excretions, and other potential hazards and choose their mask accordingly.

A face mask is considered contaminated once it has been used and should be discarded immediately. A mask should be removed by the ear loops or the ties rather than the edges or front panel.

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DECLARATION OF CONFORMITY

We declare, under our sole responsibility, that the product listed below conforms to the provisions of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Manufacturer's Name and Business Address	Sanitas Healthcare Limited The Rossi Building Unit 2, Victoria Business Park, Nottingham, UK NG4 2PA
Product Name	Protect Antiviral Type IIR Mask
Product Reference	PRT11151
Medical Device Classification	I
Classification Rule	1
GMDN Code and Term	Surgical/medical face mask, single-use – GMDN Code 35177
Standards Applied	ISO14971:2019 EN14683:2019 ISO15223:2016

Declaration made by -

Name	Role	Place and Date	Signature
M Wilkinson	Technical Manager	Daresbury, 23rd April 2021	M C Wilkinson

Declaration of Conformity

for Protect Antiviral Type IIR Mask

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Protect Antiviral Type IIR Mask
Legal Manufacturer: (Name on Label)	Sanitas Healthcare, 2 Victoria Parkway, Nottingham, NG4 2PA , UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Type IIR Facemask to prevent transmission of pathogens from the wearer to the environment, featuring an antiviral outer layer
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Mark Wilkinson **Position** Technical Director

Signed M C Wilkinson **Date** 7th May 2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 14683:2019	Medical Face Masks
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
PRT11151	Protect Antiviral Type IIR Mask	35177

Version History

Version	Compiled by	Date	Description
1.0	Mark Wilkinson	7th May 2021	First issue