

Appendix 2. VISOR -21 System

Risk analysis. Functional risks when using VISOR -21 System.

VISOR 21-System is for protection of the wearer's face, against smaller objects, direct splashes or aerosols. In case of infection, the wearing of the visor should be combined with approved respiratory protection, protective clothing and other equipment adapted to the situation. Visor -21 Systems should be checked before every use, functionally controlled and cleaned. When used in infectious disease control contexts, visor glasses, arches and straps, should be carefully wiped with disinfectant solution or replaced in case of suspected contamination, or wear. When using an optional O-9885-04 "Foampad with velour", this part must be removed/replaced after use, as it cannot be disinfected. Used protective visors may present a risk of infection, poorer optical clarity and poorer mechanical user function. All VISOR-21 System's parts should therefore be destroyed after end use, wear or after improper handling. To minimize for incorrect installation, the visor is mostly mounted and distinct instructions for fastening the visor glass are included with the product, and are available to be seen on www.plasticprodukter.se

When handling visor 21 systems in other areas, good hygiene should be observed and the protective visor handled as personal. The user should be aware of the risks of allergic reaction, in case of contact between plastic and skin. Visor -21 System is therefore manufactured in the allergy controlled material Polypropén and PET. There is a risk of neck injury when using heavier objects on the head. VISOR -21 System is therefore very light, only 74 grams..

VISOR -21 System is controlled by RISE Research Institutes of Sweden AB. Measurement Science and Technology - Time and Optics. Brinellgatan 4 SE-504 62 BORÅS. Reference number 105105-2P04978-01. The tests were performed according to EN 166:2001- Personal Eye protection. The report was written on 12/21/2020 and can be seen on www.plasticprodukter.se

Risk of storage.

In case of incorrect storage, the VISOR -21 System may be damaged. The products should therefore be stored darkly at room temperature for a maximum of 5 years. The product is dated on the outer label. Stock boxes should be placed as instructed on the packaging.

Risk when transported.

The freight packaging is specially adapted to the VISOR -21 System. Upon receipt of transport containing VISOR-21 systems, the packaging must be carefully checked. In the event of damage to the packaging, the carrier must be contacted and the shipping, and the damaged products are advertised to them.

Environmental risk.

No part or packaging of the VISOR -21 System contains substances listed in REACH, Regulation No 1907/2006 of the European Parliament and of the Council of 18 December 2006. Littering of nature and the environment may pose a risk to the inhabitants of the earth, therefore the VISOR 21 System is smartly designed for 100% recycling. Each part is easy to separate and marked with an easy-to-understand recycling symbol. Follow local regulations regarding recycling of the parts.

Risk of manufacturing failure.

VISOR-21 System, manufactured by Plastic Produkter M Bergendahl AB. To ensure the quality of production and product, underlying technical documents are stored both digitally and in paper format. Containing raw materials have specified suppliers and material data sheets. During production, every 1000'nd separate part is checked, against drawing and digital instruction. When packing, every 1000'nd is checked regarding function, appearance and packaging material, against function descriptions and packing instructions. Alternative raw material supply of equivalent input materials is available. Production is made in, commonly used on the market, available raw materials, PET, PP and TPE/

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