

Product Data Sheet – FFP2

The Dutch PPE Solutions **Type FFP2 Mask**, provides a sufficient barrier to minimize the direct transmission of aerosols and respiratory droplets. The Dutch PPE Solutions Type FFP2 Mask is in conformity with Medical Device Directive, Annex VII and Regulation (EU) 2016/425 & 93/42/EC and the requirements of EN149:2001+A1:2009. Notified Body: BSI Netherlands, 2797.

Key Features



Latex free



Enhanced breathability



Adjustable



Less eyewear fogging



Technical Summary

Regulations

MDD 93/42/EC , 2007/47/EC	Medical Devices Directive
EN 149:2001 + A1:2009 (cf (EU)2020/403)	Respiratory protective devices
EU 2016/425	Personal Equipment Regulation
ISO 15223-1:2016	Medical devices – Symbols to be used with medical devices, labels, labelling and information to be supplied. Part 1: General requirements.
EN 1041+A1:2013	Information supplied by the manufacturer of medical devices.
EN 14971:2019	Medical Devices – Application of Risk Management
ISO 10993-10:2013	Biological evaluation of medical devices. Part 10: Test for irritation and skin sensitization.
ISO 16142-1:2016	Medical devices-Recognized essential principles of safety and performance of medical devices. Part 1: General essential principles and additional specific principles for all non-IVD medical devices guidance on the selection of standards.
EN 62366-1:2015	Medical devices. Part 1: Application of usability engineering to medical devices
GMDN	35177
CE	CE 2797

Material

Product Part	Material and Characteristics
First layer	Spunbond PP nonwoven fleece, orange
Second layer	Meltblown PP nonwoven, white
Third layer	Colback nonwoven
Fourth layer	Spunbond PP hydrophobic, white
Head loop	Nylon/Spandex
Nose clamp	Aluminum (between the nonwoven layers)

Packaging

Package	Material	Size (L x W x H) mm
Single Pack	Not available	Not available
Dispenser Pack (25 Pieces)	Carton, FSC	140x130x180mm
Transport Carton (24 dispensers)	Cart board	560x395x375

EAN-13 symbol GS1 productcode (GTIN):
8720299263406

Productdiscription: Filtering half mask FFP2
Net content: 25 1N
Brand: Dutch PPE Solutions
Product Specifications: 10005844 – Medical devices



EAN-13 symbol GS1 productcode (GTIN):
8720299263413

Productdiscription: Filtering half mask FFP2
Net content: 600 1N
Brand: Dutch PPE Solutions
Product Specifications: 10005844 – Medical devices



Warnings and Recommendations

Warning	
Usage	Dutch PPE Solutions Type FFP2 mask is a single use product.
Storage	<80% humidity & Temp -20/+25
Shelf Life	2 years