

EU Type Examination Certificate

This is to certify that:

MEDOP SA
Bruno Mauricio Zabala, 16-4º izq
BILBAO VIZCAYA
48003
Spain

Holds Certificate Number:

CE 723308

In respect of:

Filtering masks to protect against particles - to EN 149:2001+A1:2009 Models: 902889, 908158, 910339, 910578, 911160. SERIE 4P (912463, 912464, 912465, 912466, 912467, 912468 and 912469).

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2020-04-09

Latest Issue: 2020-04-09

Drs. Dave Hagenaaars, Managing Director

Effective Date: 2020-04-09

Expiry Date: 2025-04-09

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EU Type Examination Certificate

No. CE 723308

Product Details

Product Type: Filtering half masks to protect against particles.

Models:

902889	912463	912468
908158	912464	912469
910339	912465	
910578	912466	
911160	912467	

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.

EN 149 Classifications: See Product Specific Information.
In the Table the Classification references are as follows:
FFPX indicates the penetration class of the product's filter material
NR indicates the product is a single shift device
D indicates the product meets the Clogging Option.

Product Specific Information

Model	Description	Classification
902889	Conical mask with exhalation valve	FFP2 NR
908158	Large range conical mask with activated charcoal layer and exhalation valve.	FFP2 NR D
910339	Large range conical mask with exhalation valve.	FFP3 NR D
910578	Vertical fold flat mask with activated charcoal layer and exhalation valve.	FFP2 NR
911160	Conical mask with exhalation valve.	FFP1 NR
912463	Cymbiform Foldable HY9300 Range with clogging.	FFP1 NR D
912464	Cymbiform Foldable HY9300 Range with clogging - Mask with exhalation valve fitted.	FFP1 NR D
912465	Cymbiform Foldable HY9300 Range with clogging.	FFP2 NR D
912466	Cymbiform Foldable HY9300 Range with clogging - Mask with exhalation valve fitted.	FFP2 NR D
912467	Cymbiform Foldable HY9300 Range with clogging.	FFP3 NR D
912468	Cymbiform Foldable HY9300 Range with clogging - Mask with exhalation valve fitted.	FFP3 NR D
912469	Cymbiform Foldable HY9300 Range with clogging - Mask with activated charcoal and exhalation valve fitted.	FFP3 NR D

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Certificate Administration Details

Product initially approved on BSI Certificate CE 690991

Certificate Amendment Record

Issue date	Comments	BSI Review No.
April 2020	First issue to PPE Regulation 2016/425. The products were previously certified to the PPE Directive 89/686, BSI issued Certificate CE 572123 refers.	2797:20:3126420
May 2020	Additional products added which were previously certified to the PPE Directive 89/686, BSI issued Certificate CE 572123 refers.	2797:20: 3217862

Certificate validity:

The Certificate holder is responsible for ensuring the Notified Body advised of changes to any aspect of the overall process utilized in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to type based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI Issued Certificate CE 79995.

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