

# EU Type Examination Certificate

This is to certify that:

3M United Kingdom Plc  
3M Centre  
Cain Road  
Bracknell  
Berkshire  
RG12 8HT  
United Kingdom

Holds Certificate Number: CE 705693

In respect of:

**Respiratory protective devices to EN 149:2001+A1:2009 -  
Filtering half masks to protect against particles  
Models: 3M™ VFlex™ Particulate Respirators  
9152/9152S and 1802/1802S**

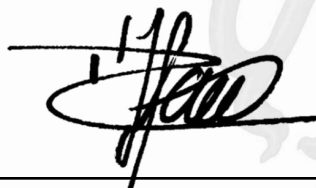
on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements 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: 2019-04-03

Latest Issue: 2019-10-29



Drs. Dave Hagenaaers, Managing Director

Effective Date: 2019-10-29

Expiry Date: 2024-04-03

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No. CE 705693

## Product Specification

**Product Name:** 3M™ VFlex™ Particulate Respirators.

**Product Type:** Filtering half masks to protect against particles.

**Models:** 9152/9152S (standard industrial product)  
1802/1802S (healthcare product).

**Technical Specification:** Personal Protective Equipment Regulation Harmonized European Standard: EN 149:2001+A1:2009.  
Medical Devices Directive Harmonized European Standard: EN 14683:2005 (for 1802/1802S).

**Product Description:** The particulate respirators are designed to protect against solid and non-volatile liquid particles only. The masks are held on the face by a pair of elasticated straps, each model is also available small size (S). The models 1802 and 1802S are surgical masks for use to limit the transmission of infective agents from staff to patients. The models are single shift devices (denoted by the classification symbol NR) and have the Dolomite Clogging option (denoted by the classification symbol D).

<b>Product Classification:</b>	<b>Model</b>	<b>EN 149 Classification</b>	<b>EN 14683 Classification</b>
	9152/9152S	FFP2 NR D	
	1802/1802S	FFP2 NR D	Type II.

## Product Assessment

The product assessments were based on BS EN 149:2001+A1:2009, the English language version of EN 149:2001+A1:2009, respiratory protective devices – filtering half masks to protect against particles, both documents incorporating Corrigendum dated July 2002.

For 1802/1802S additional product assessments were based on EN 14683:2005, surgical masks. 3M has Self Certified these products to the requirements of Annex VII of the European Community Directive 93/42/EEC (Medical Devices Directive) as a Class 1 device.

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## Packaged variants

In addition to the products referenced on this Certificate the standard industrial products may also be sold as market specific packaged variants. Such variants will be differentiated and the Technical File(s) will be updated with the appropriate information.

## Kits and packouts

The products referenced on this Certificate may also be combined with other 3M products into a kit or packout. There will be no change to the product but the User Information may vary, in such instances the applicable Technical File(s) will be updated with the appropriate information.

## Certificate Administration Details

Technical File Reference: TF0530

## Certificate Amendment Record:

Issue date	Comments	BSI Review No.
April 2019	First issue under PPE Regulation (EU) 2016/425. Note: Products initially approved to Module B off PPE Regulation by a different Notified Body.	0086:19:9704731

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised 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 595701.

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