

EU Type Examination Certificate

This is to certify that:

BAB-Medical BV
Millenerweg
2/2A
Sittard
6136 KW
The Netherlands

Holds Certificate Number:

CE 741971

In respect of:

**Model SGM1 Particulate Respirator to Technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by the healthcare professionals as per commission recommendation 2020/403**

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):

Drs. Dave Hagenaaars, Managing Director

First Issued: 2021-03-05
Latest Issue: 2021-03-05

Effective Date: 2021-03-05
Expiry Date: 2022-03-05

Page: 1 of 3



...making excellence a habit.™

EU Type Examination Certificate

No. CE 741971

Product Specification

Product Name: Particulate Respirator

Product Type: Particulate filtering half mask for use by Healthcare professionals.

Models: **SGM1**

Classification: FFP2 NR un-valved.

Technical Specification: Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

Product Description:

The respirator is non-reusable, secured to the face of the user by a pair of elasticated ear straps, and have no exhalation valve. The respirator is FFP2 class.

The respirator listed on this certificate is for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread.

The product covered by this certificate is not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.

Product Assessments: BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

First Issued: 2021-03-05

Latest Issue: 2021-03-05

Effective Date: 2021-03-05

Expiry Date: 2022-03-05

Page: 2 of 3

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

EU Type Examination Certificate

No. CE 741971

Certificate Administration Details

Technical File Reference: FI2021

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
March 2021	First issue.	2797:21: 3347466

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 Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 741972

First Issued: 2021-03-05

Latest Issue: 2021-03-05

Effective Date: 2021-03-05

Expiry Date: 2022-03-05

Page: 3 of 3

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.