EU Type Examination Certificate

This is to certify that:

Theo Manufacturing B.V.
Sleperweg 44
Maastricht
6222 NK
The Netherlands

Holds Certificate Number: CE 731248

In respect of:

Models 800.01 Face mask.
To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by 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):

5.1.2e 5.1.2e 5.1.2e

First Issued: 2021-02-09
Latest Issue: 2021-02-09

Effective Date: 2021-02-09
Expiry Date: 2022-02-09

PRODUCTS RvA C 646

...making excellence a habit.™

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 731248

Product Specification

Product Name:	Particulate Respirator/ Face Mask
Product Type:	Particulate filtering half masks for use by Healthcare professionals.
Model:	**800.01**
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 has 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: 2021-02-09
Latest Issue: 2021-02-09

Effective Date: 2021-02-09
Expiry Date: 2022-02-09

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 731248

Certificate Administration Details

Technical File Reference: Technical File for model 800.01

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
February 2021	First issue.	2797:21:3249035

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 731249.

First Issued: 2021-02-09
Latest Issue: 2021-02-09

Effective Date: 2021-02-09
Expiry Date: 2022-02-09

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.

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

This is to certify that:

Theo Manufacturing B.V.
Sleperweg 44
Maastricht
6222 NK
The Netherlands

Holds Certificate Number: CE 731249

In respect of:

For the manufacture of particulate respirators to technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

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

5.1.2e

First Issued: 2021-02-09
Latest Issue: 2021-02-09

Effective Date: 2021-02-09
Expiry Date: 2022-02-09

PRODUCTS
RvA C 646

...making excellence a habit.™

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.

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

No. CE 731249

Product manufactured by:

Theo Manufacturing B.V.
Sleperweg 44
Maastricht
6222 NK
The Netherlands

Product details

The respiratory protective device covered by the scope of this Module C2 Certificate and the Technical Specification to which the product is manufactured are as follows:

Product type:	Particulate filtering half masks for use by Healthcare professionals.
Model and classifications:	800.01 FFP2 NR
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

Certificate Administration Details:

Certificate Amendment Record and BSI internal Review relating to this Certificate

Issue date	Comments	BSI Review No.
February 2021	First issue.	2797:21:3249036

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

First Issued: 2021-02-09
Latest Issue: 2021-02-09

Effective Date: 2021-02-09
Expiry Date: 2022-02-09

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.