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

This is to certify that:

Medical Devices Technology
International Limited
Kace Building, Victoria Passage
Wolverhampton
WV1 4LG
United Kingdom

Holds Certificate Number: CE 730969

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):

Drs. Dave Hagenaars, Managing Director

First Issued: 2020-09-11
Latest Issue: 2020-09-11

Effective Date: 2020-09-11
Expiry Date: 2021-09-11



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No. CE 730969

**Product manufactured by:**

Guangdong Donghua Optoelectronics Technology Co. Ltd,
Kengkou Industrial Zone
Dean Village, Houjie Town
Dongguan
Guangdong
China

**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:** | KN95 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. |

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**Certificate Administration Details:**

**Certificate Amendment Record and BSI internal Review relating to this Certificate**

| Issue date | Comments | BSI Review No. |
|---|---|---|
| September 2020 | First issue. | 2797:20: 3224581 |

**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.

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