



Gentex Europe

Unit 3, Focus 4, Fourth Avenue
Letchworth Garden City
Herts
SG6 2TU
United Kingdom
Phone: +44 (0) 1462 478000
Fax: +44 (0) 1462 478010

EU Declaration of Conformity

1. Respiratory Mask:
 - a. HM1500 Medi Mask
2. Respiratory Filters:
 - a. P3 R Particulate Inhalation Filter 'F1200 Inhale Filter'
3. Manufacturer: Helmet Integrated Systems Ltd, Unit 3 Focus 4, Fourth Avenue, Letchworth Garden City, Herts, SG6 2TU United Kingdom (products use Corpro branding)
4. This declaration of conformity is issued under the sole responsibility of the manufacturer.
5. Object of Declaration:
 - a. FDC Part Numbers
 - i. HM1500
 - ii. F1200 Inhale Filter P3 R
 - b. Batch number convention XXXYYYY/ZZ were
 - i. XXX= Last 3 digits of part number.
 - ii. YYYY= Batch number, e.g. 0001, 0002, 0003, etc.
 - iii. ZZ= Week number, e.g. 01,02,03, etc
 - c. Photos
 - i. HM1500
 - ii. F1200 Inhale Filter
6. The objects of declaration in point 4 are in conformity with the relevant Union harmonisation legislation: Regulation (EU) 2016/425
7. Relevant harmonized standards used: EN 143:2021 regarding the F1200 Inhale Filter. EN140:1998 regarding the HM1500.
8. The PPE is subject to the conformity assessment procedure conformity to type based on EU Regulation 2016/425 Type-Examination (Module B) Certified by BSI Group the Netherlands B.V., Say Building, John M Keynesplein 9, Amsterdam, The Netherlands, NB 2797 (Certificate number CE 761168), who are also responsible for the ongoing quality surveillance Module D.

This correspondence is from Helmet Integrated Systems Ltd., registered in England and Wales (with company registration number 2766754), and with a registered office at Unit 3, Focus 4, Letchworth Garden City, Hertfordshire, SG6 2TU, UK. Helmet Integrated Systems Ltd., is wholly owned by Gentex Corporation.

Signed for and on behalf of Gentex Europe

St Helens, December 2023

Name: ROBERT SWINEN

Function: DIRECTOR

Signature: 

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