



EC Declaration of Conformity

Manufacturer: Tecman Speciality Materials Ltd

Address: Berrington House, Berrington Road, Leamington Spa, CV31 1NB, UK

Product Description: Type IIR Face Mask

Product Code: TEC_MASKL_01
TEC_MASKT_01
TEC_MVIST_01
TEC_MVISL_01

Medical Device classification: Class I, under Annex IX, Council Directive 93/42/EEC


GMDN Code: 35177 - Surgical/medical face mask, single-use

Conformity Assessment Route: Annex VII, Council Directive 93/42/EEC

Standards Applied: BS EN14683:2019
BS EN ISO 15223-1:2016
BS EN 1041:2008+A1:2013
ISO 10993-1:2020
ISO 13485:2016
ISO 9001:2015
ISO 14971:2019

This declaration of conformity is issued under the sole responsibility of the manufacturer. We hereby declare that the above products, placed on the market from the 7th June 2021, meet the provisions of the Medical Device Directive (MDD) (Council Directive 93/42/EEC, as amended and transposed into national law where the products are marketed).

Date of Issue: 07/06/2021
Date of Expiration: 07/06/2025



Kevin Porter

Tecman Speciality Materials Ltd
Technical MD

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