

GERSON®

EU Declaration of Conformity

Type of Equipment: Personal protective equipment, category FFA2P2 NR

Product Description(s):

One-Step Disposable Kit – TPE Half-Mask with A2P2 NR -SM
One-Step Disposable Kit – TPE Half-Mask with A2P2 NR -MED
One-Step Disposable Kit – TPE Half-Mask with A2P2 NR -LG

Model Number(s):

8111E2
8211E2
8311E2

Manufacturer:

Louis M. Gerson Co., Inc.
16 Commerce Blvd.
Middleboro, MA 02346 USA

This declaration of conformity is used under the sole responsibility of the manufacturer.

The equipment is in conformity with the relevant Union harmonization legislation:

EU 2016/425 Personal Protective Equipment

Harmonized standard(s) used for demonstration of compliance:

EN 405:2001+A1 2009 Respiratory protective devices – Valved filtering half masks to protect against gases or gases and particles – Requirements, testing, marking

The notified body, CCQS Certification Services Limited, Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin. D15 AKK1 (Notified Body No. 2834) performed the EU type-examination (Module B) and issued the EU type-examination certificate of conformity CE-PI-20230116-01-01-9B.

The equipment is subject to the requirements set out in Module D of EU Regulation 2016/425 under the surveillance of CCQS Certification Services Limited, (Notified Body No. 2834) as of the 13th August, 2023 as detailed in certificate number CE-PI-20230130-01-FPC-B. This certification was previously issued by INSPEC International B.V. (Notified Body No. 2849) as detailed in certificate number D-PPE19171045.

Signed for and on behalf of:

Louis M. Gerson Co., Inc.,
16 Commerce Blvd,
Middleboro, MA 02346, USA

Date: 07/09/24


Abigail Keaveney
Sr. Director/Head of Global
Quality and Regulatory Affairs