

**DECLARATION OF CONFORMITY**

We

**MANUFACTURER'S NAME:**

Pharmaplast SAE

**MANUFACTURER'S ADDRESS:**

**Site 1:** Amria Free Zone, 23512, Alexandria, Egypt.

**Site 2:** Madinet Borg Al Arab, Qesm Borg Al Arab Alexandria, Egypt.

**AUTHORIZED REPRESENTATIVE'S NAME:**

E C Rep Ltd,

**AUTHORIZED REPRESENTATIVE'S ADDRESS:**

5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland.

Tel: +353 1 2 544 944

Email: info@ecrep.ie

Declares that the products covered by this declaration are in compliance with requirements of Annex II and Annex IX of Regulation (EU) 2016/425 and the harmonized standard EN 149:2001+A1:2009, and are manufactured and placed in the market under the sole responsibility of the manufacturer following the requirements of this Regulation.

**Product information:**

**Name:** 1- Pharmaplast Filtering Half Mask, folded cup style (white and colored).

2- Boots Protective FFP2 NR facemasks.

**Protection Class:** FFP2 NR

**Models:**

| Model                                   | Model Code | Pieces/ Box | Boxes/Case |
|---|------------|-------------|------------|
| FFP2 (94%) ear loop (white and colored) | FC-F2E     | 50          | 10         |
| FFP2 (94%) head band                    | FC-F2H     | 50          | 10         |
| FFP2 (94%) ear loop - Boots             | FC-F2E     | 5           | 24         |

**Classification:**

Pharmaplast Filtering half mask is classified as Personal Protective Equipment, Category III according to Annex I of (EU) 2016/425.

The notified body:

**Name:** MNA LABORATUVARLARI SANAYI TICARET LIMITED ŞİRKETİ

**Address:** Küçükbakkalköy Mah. Yenidoğan Cad. No: 21, Ataşehir/İstanbul, Turkey

**Identification Number:** CE2841

Performed the EU type-examination (module B according to Annex V) and issued the EU type-examination certificate no. :

| Model        | Certificate number |
|--------------|--------------------|
| FC-F2E       | 61-20-01-R02       |
| FC-F2H       | 61-20-03-R01       |
| Boots FC-F2E | 299-21-01          |

The PPE is subject to the conformity assessment procedure: conformity to type based on internal production control plus supervised product checks at random intervals (module C2) according to Annex VII under surveillance of the notified body:

**Name:** MNA LABORATUVARLARI SANAYI TICARET LIMITED ŞİRKETİ

**Address:** Küçükbakkalköy Mah. Yenidoğan Cad. No: 21, Ataşehir/İstanbul, Turkey

**Identification Number:** CE2841

| Name, Job title | Signature        | Place             | Date       | Version |
|-----------------|------------------|-------------------|------------|---------|
| Dina Aziz       | <i>Dina Aziz</i> | Alexandria, Egypt | 16.04.2022 | 09      |

**Company Stamp**



**Change History:**

| Version Number | Date       | Change   | Rationale for Change  |
|----------------|------------|--|---|
| 01             | 21.10.2020 | First issue  | First issue   |
| 02             | 02.11.2020 | Change Certificate number                              | Certificates have been updated                                    |
| 03             | 03.11.2020 | Adding 2 additional manufacturing site                 | 2 additional manufacture sites have been added to the certificate |
| 04             | 19.12.2020 | Change EN 149:2001+AC: 2019 to be EN 149:2001+AC: 2009 | Typing mistake  |
| 05             | 30.01.2021 | Change EN 149:2001+AC: 2009 to be EN 149:2001+A1: 2009 | Typing mistake  |
| 06             | 29.03.2021 | Add 2 new models: FC-F2EK<br>FC-F2EKV                  | 2 new models have been added to product range.                    |
| 07             | 13.01.2022 | Remove FC-F2EKV and add Boots FC-F2E                   | FC-F2EKV is cancelled<br>Boots FC-F2E is added to the scope       |
| 08             | 20.03.2022 | Remove FC-F2EV and FC-F2HV                             | Both models have been cancelled                                   |
| 09             | 16.04.2022 | Amend Module B certificate for FC-F2E                  | New update of the certificate                                     |