

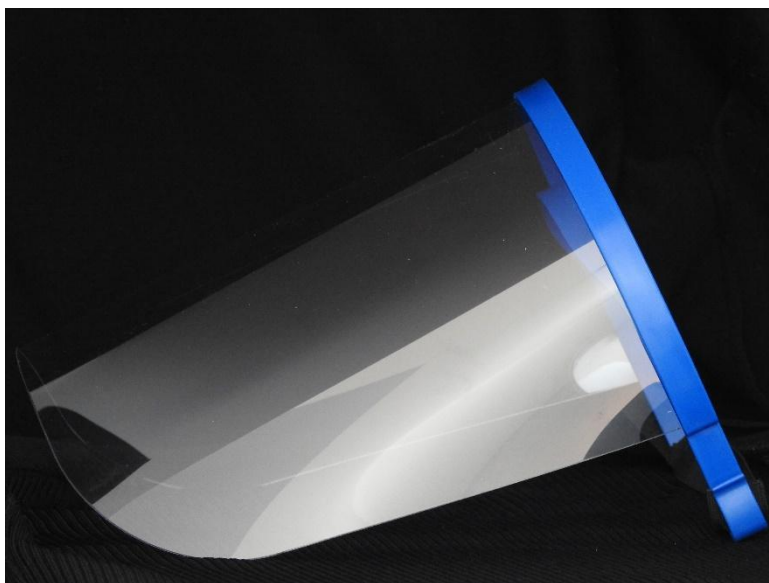
## Declaration of Conformity

for the Protective Face Shield

### Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 concerning Personal Protective Equipment (PPE)

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed. This declaration of conformity is issued under the sole responsibility of the manufacturer indicated below.

<b>Product</b>	Protective Face Shield, ref. number 2058
<b>Legal Manufacturer: (Name on Label)</b>	<b>MA-COM doo</b> Gospodarsko-poslovna zona Hodovo bb, 88 360 Stolac, Bosnia and Herzegovina
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>PPE Category:</b>	Category II
<b>Notified Body:</b>	APAVE SUDEUROPE SAS. 0082
<b>EU Authorised Representative:</b>	<b>Advena Limited</b> Tower Business Centre, 2 <sup>nd</sup> Floor, Tower Street, Swatar, BKR 4013, Malta
<b>Conformity Assessment Procedure:</b>	EU Type Certification



**Name** IVICA VRLJIČAK

**Position** Managing Director

**Signed**



**Place &  
Date**

Stolac, April 1st, 2023

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

**Appendix I – Applicable Standards**

The object of the declaration described above is in conformity with the relevant Union harmonised legislation:

<b>Standard/Document Name</b>	<b>Description</b>
2016/425	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 concerning PPE
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN 166:2001	Personal eye - protection - Specification

**Appendix II – Product Listing/Schedule**

<b>Catalogue Number</b>	<b>Device Name</b>	<b>GMDN Code</b>
2058	Face splash shield, reusable	64779

**Version History**

<b>Version</b>	<b>Compiled by</b>	<b>Date</b>	<b>Description</b>
Version 1	Martina Perić	August 17 <sup>th</sup> , 2020	
Version 1.1.	Sanda Kolobara	April 1 <sup>st</sup> , 2023.	