



## ES IZJAVA O SKLADNOSTI / EC DECLARATION OF CONFORMITY

Skladno z / According to the: Uredbo / Regulation (EU) 2017/745

izdana pod izključno odgovornostjo proizvajalca, ki je naveden spodaj / issued under the sole responsibility of the manufacturer, stated below:

|                                                                                   |                                                                                                |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>Proizvajalec / Manufacturer</b>                                                | UTG VODNIK d.o.o.<br>Tolstojeva ulica 12, Vir, 1230 Domžale, Slovenia                          |
| <b>SRN</b>                                                                        | še ni dodeljene / not yet assigned                                                             |
| <b>Proizvodna enota /<br/>Manufacturing unit</b>                                  | Pod lipami 10, 1218 Komenda, Slovenia                                                          |
| <b>Naziv izdelka / Product Name</b>                                               | Medicinska obrazna maska za enkratno uporabo, troslojna<br>Single-use Medical Face Mask, 3 ply |
| <b>Model/tip / Model/Type</b>                                                     | tip II / Type II                                                                               |
| <b>Osnovni UDI / Basic UDI</b>                                                    | 383007678MASK21141817JE                                                                        |
| <b>Generično ime / Generic Name</b>                                               | Medicinska obrazna maska / Medical Face Mask                                                   |
| <b>Razvrstitev / Classification</b>                                               | I (skl. z / acc. to: Dodatek VIII / Annex VIII)                                                |
| <b>Pravilo, uporabljeno za<br/>razvrstitev / Rule used for<br/>classification</b> | Pravilo 1 / Rule 1 (skl. z / acc. to: Dodatek VIII / Annex VIII)                               |
| <b>Druga imena / Alternative name(s) /</b>                                        |                                                                                                |

Podjetje UTG VODNIK d.o.o. izjavlja, da so zgoraj navedeni izdelki skladni z zahtevami Uredbe o medicinskih pripomočkih (EU) 2017/745 in z drugimi določbami ustrezne zakonodaje Unije, ki določa izdajanje izjave EU o skladnosti.

Company UTG VODNIK d.o.o. hereby declares, that the above-mentioned products are in conformity with the requirements of the Medical Device Regulation (EU) 2017/745 and any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

|                                                      |                                                                                  |
|------------------------------------------------------|----------------------------------------------------------------------------------|
| <b>Uporabljeni standardi /<br/>Standards applied</b> | EN 14683:2019+AC:2019, EN ISO 14971:2019,<br>EN ISO 15223-1:2016, ISO 13485:2016 |
| <b>Priglašeni organ /<br/>Notified body</b>          | /                                                                                |
| <b>EC certifikat / EC certificate</b>                | EC certificate number: /<br>Date issued: /<br>Valid until: /                     |

Kraj in datum izdaje /  
Issue place and date:

Domžale, 06.07.2020



Vir, Tolstojeva 12, 1230 Domžale  
ID za DDV: SI47451742

Podpis / Signature

Uroš Vodnik, direktor / General Manager