



IZJAVA EU O SKLADNOSTI / EU DECLARATION OF CONFORMITY

Skladno z / According to the: Uredbo / Regulation (EU) 2017/745
verzija / version 2-2020

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

Proizvajalec / Manufacturer	UTG VODNIK d.o.o. Tolstojeva ulica 12, Vir, 1230 Domžale, Slovenia
SRN	/
Proizvodna enota / Manufacturing unit	Pod lipami 10, 1218 Komenda, Slovenia
Naziv izdelka / Product Name	Medicinska obrazna maska za enkratno uporabo, troslojna-333383 Medical Face Mask Single-use 3 ply-333383
Model/tip / Model/Type	tip II / Type II
Osnovni UDI / Basic UDI	383007678MASK21141817JE
Generično ime / Generic Name	Medicinska obrazna maska / Medical Face Mask
Razvrstitev / Classification	I (skl. z / acc. to: Dodatek VIII / Annex VIII)
Pravilo, uporabljeno za razvrstitev / Rule used for classification	Pravilo 1 / Rule 1 (skl. z / acc. to: Dodatek VIII / Annex VIII)
Druga imena / Alternative name(s) /	

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.

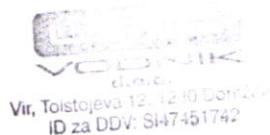
Company UTG VODNIK d.o.o. hereby declares, that the above-mentioned products are in conformity with the requirements of the Medical Device Regulation (EU) 2017/745 and any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

**Uporabljeni standardi /
Standards applied**

EN 14683:2019+AC:2019, EN ISO 14971:2019,
EN ISO 15223-1:2016, ISO 13485:2016

**Kraj in datum izdaje /
Issue place and date:**

Domžale, 09.09.2020



Podpis / Signature

Uroš Vodnik, direktor / General Manager