



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:

Proizvajalec / Manufacturer	UTG VODNIK d.o.o. Tolstojeva ulica 12, Vir, 1230 Domžale, Slovenia
SRN	še ni dodeljene / not yet assigned
Naziv izdelka / Product Name	Medicinska obrazna maska za enkratno uporabo, troslojna (tip II) / Single-use Medical Face Mask, 3 ply (Type II)
Model/tip / Model/Type	tip II - št. artikla 333383 / Type II - article nr. 333383
Razvrstitev / Classification Pravilo, uporabljeno za razvrstitev / Rule used for classification	I (skl. z / acc. to: Dodatek VIII / Annex VIII) 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
Priglašeni organ / Notified body	/
EC certifikat / EC certificate	EC certificate number: / Date issued: / Valid until: /

Kraj in datum izdaje /
Issue place and date:

Podpis / Signature

Domžale, 06. 07. 2020

Uroš Vodnik, direktor / General Manager