253 | Neolution®Air Loop | Izjava EU o skladnosti / EU Declaration Of Conformity

OVO, MP, Predmet izjave / *PPE, MD, Object of Declaration*

REF	253
Osnovni UDI-DI *Basic UDI-DI*	4049825MEDMASKS4G
Naziv izdelka / *product name*	Neolution®Air Loop
Izdelek / *Product*	*Respirator*

Proizvajalec in odgovornost / *Manufacturer & Responsibility*

DACH Schutzbekleidung GmbH & Co. KG
Rotackerstr. 21
D-76437 Rastatt
SRN: DE-MF-000014734

Ta izjava o skladnosti je izdana na izključno odgovornost proizvajalca.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Harmonizirana zakonodaja unije / *Union Harmonisation Legislation*

Ta izdelek je osebna varovalna oprema **kategorije III** v skladu s Prilogo I Uredbe (EU) 2016/425 in medicinski pripomoček **razreda I** v skladu s Prilogo VIII Uredbe (EU) 2017/745.

*This product is **Category III** Personal Protective Equipment according to Annex I of Regulation (EU) 2016/425 and **Class I** Medical Device according to Annex VIII of Regulation (EU) 2017/745.*

Harmonizirani standardi, tehnične specifikacije / *Harmonised Standards, Technical Specifications*

Izdelek izpolnjuje zahteve za respiratorje FFP2 NR D po standardu EN 149:2001+A1:2009. Prav tako izpolnjuje zahteve za medicinske obrazne maske tipa IIR v skladu s standardom EN 14683:2019+AC:2019 glede učinkovitosti bakterijske filtracije (Bacterial Filtration Efficieny), odpornosti proti pljuskom/škropljenju (Splash Resistance) in mikrobne čistosti (Microbial Cleanliness).

The product meets the requirements for FFP2 NR D respirators according to the EN 149:2001+A1:2009 standard. Additionally meets the requirements for Type IIR medical face masks according to the EN 14683:2019+AC:2019 standard in terms of filtration efficiency for bacteria, splash resistance pressure and microbiological cleanliness.

Priglašeni organ / *Notified Body*

Priglašeni organ AITEX št. 0161 je izvedel EU-pregled tipa (modul B) in izdal certifikat o EU-pregledu tipa št. 22/4849/02/0161.

The notified body AITEX, No. 0161, performed the EU type-examination (Module B) and issued the EU type-examination certificate No. 22/4849/02/0161.

Postopek ugotavljanja skladnosti / *Conformity Assesment Procedure*

Osebna varovalna oprema je predmet postopka ugotavljanja skladnosti: Skladnost s tipom na podlagi notranje kontrole proizvodnje in nadzorovanih pregledov izdelka v naključnih intervalih (Modul C2) pod nadzorom priglašenega organa AITEX, št. 0161.

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) under surveillance of the notified body AITEX, No. 0161.

Podpisano za in v imenu *Signed for and on behalf of*	*DACH Schutzbekleidung GmbH & Co. KG, Rastatt*	**Ioannis Okoutsidis** Tehnični direktor / *Technical Director*	I. Okoutsidis