PPE Regulation (EU) 2016/425

EU DECLARATION OF CONFORMITY No PPE-01

- 1. PPE (product, type, batch or serial number): <u>Coverall, with hood, with boot, zip front opening covered by a flap closure with adhesive tape, is made of fabric PP laminated with microporous film.</u>
- 2. Name and address of the manufacturer:

<u>Unimax Medical Products Co., Ltd Special No.1 Liansai Road, Changshangkou Town, 433024, Xiantao City, Hubei Province, People's Republic of China</u>
Where applicable, his authorised representative: <u>SUNGO Europe B.V.</u>

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

- 3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Unimax Medical Products Co., Ltd
- 4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):
 Coverall made of fabric PP laminated with microporous film is chemical protective coverall gives protection for the wearer from hazardous agents including airborne particulates & dusts, limited liquid splash &sprays, biological hazards & infective agents and electrostatic shock.
- 5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation (EU) 2016/425.
- References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared: <u>EN 13982-1:2004, EN 13034:2005, EN 14126:2003,</u> EN1149-1:2006, EN ISO 13688:2013
- 7. Where applicable, the notified body <u>BTTG Testing & Certification No. 0338(name, number)</u> performed the EU type-examination (Module B/<u>Article 10)</u> and issued the EU type-examination certificate 522676/1 (reference to that certificate).
- 8. Where applicable, the PPE is subject to the conformity assessment procedure <u>Module D</u>(either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) under surveillance of the notified body <u>BTTG Testing & Certification No. 0338</u> (name, number).
- 9. Additional information:

Signed for and on behalf of: Unimax Medical Products Co., Ltd

(place and date of issue): Wuhan, January 28, 2021

(name, function) (signature): XIA XINMING

General Manager---XIA XINMING

For and on behalf of UNIMAX MEDICAL PRODUCTS CO., LTD. 聯賽費用產品(湖北)有限公司

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