portavita

EU DECLARATION OF CONFORMITY No 205/06/2020

1. This declaration of conformity is issued under the sole responsibility of the manufacturer: "Portavita" SRL

2. Object of the declaration: Protective Coverall ZC3B-53L

3. The object of the declaration described is in conformity with the relevant Union harmonisation legislation:

- The technical design of the PPE meets the requirements of the Regulation (EU) 2016/425 that apply to it, taking into account the intended use claimed by the manufacturer
- The PPE type complies with the applicable essential health and safety requirements set out in Annex II of the regulation (EU) 2016/425, wich apply to it, taking into account the intended use claimed by the manufacturer
- PPE conforms to the following harmonized standards: SR EN 13034+A1:2010 (EN 13034:2005+A1:2009), Type 6, SR EN ISO 13688:2013 (EN ISO 13688:2013, SR EN 14325:2004 (EN 14325:2004)

4. 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:

PPE conforms to the following harmonized standards: SR EN 13034+A1:2010 (EN 13034:2005+A1:2009), Type 6, SR EN ISO 13688:2013 (EN ISO 13688:2013)
Surgical clothing and drapes. Requirement and test methods. Part 1: Surgical drapes and glowes SM EN 13795-1:2019)

5. Where applicable, the notified body NB:2756 performed the EU type-examination: Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, annex V "EU type-examination (Module B) and issued the EU type-examination certificate No. 3545/EIP/28.05.2020.

6. References for the conformity assesmnet/certification:

a) Procedures of the notified body: general procedure: "PPE conformity assessment applying the procedure "EU type-examination (Module B)" referred to in Relation (EU) 2016/425, PG EIP R MODUL B and specific procedure for protective clothing, PSC EIP R-05.
b) Health and safety requirements to be met by the model: set out in Annex II of the Regulation (EU) 2016/425, wich apply to it, taking into account the intended use claimed by the manufacturer, respectively the requirements:
-GENERAL REQUIREMENTS APPLICABLE TO ALL PPE: 1.1 (Design principles); 1.1.1 (Ergonomics); 1.1.2 (Levels and classes of protection) 1.1.2.1 (Optimum level of protection); 1.1.2.2. (Classes of protection appropriate to different levels of risk); 1.2.1.1 (Suitable constituent materials); 1.2.1.2 (Satisfactory surface condition of all PPE parts in contact with the user); 1.2.1.3 (Maximum permissible use impediment); 1.3 (Comfort and effectiveness); 1.3.1 9 (Adaptation of PPE to user morphology); 1.3.2. (Lightness and strength); 1.4 (Manufacturer's instruction and information);
-ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE: 2.2 9PPE enclosing the parts of the body to be protected); 2.4 (PPE subject to ageing); 2.12 (PPE bearing one or more identification markings or indicators directly relating to health and safety);
-ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS: 3.3 (Protection against mechanical injuries)-superficial mechanical injury, minor risks; 3.10 (Protection against substances and mixtures which are hazardous to health and against harmful biological agents); 3.10.2 (Protection against cutaneous and ocular contact)

28.05.2020

Lilia Ranogaet, Director