



In application of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorized by the FPS Economy (Federal Public Services) has issued the following:

EU TYPE EXAMINATION CERTIFICATE

Nr. 086/2018/0204

This EU Type examination certificate is valid until 21 Apr 2023

This certificate is valid from 21 Apr 2018.

to: **Ultra Medical Care Co., Ltd**

for: **UltraMedical® 250**

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

For the argumentation, the following standards are used:

EN 1149-5:2008	Protective clothing - Electrostatic properties - Part 5: Material performance and design requirements
EN 13034:2005+A1:2009	Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB(6))
EN ISO 13982-1:2004+A1:2010	Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)
EN 14126:2003	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN ISO 13688:2013	Protective clothing - General requirements
EN 1073-2:2002	Protective clothing against radioactive contamination - Part 1 : Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination

If there is a former EC Type examination certificate according to the Directive 89/686/EEC this certificate remains valid until 21 April 2023 unless it expires before that date, for products that were manufactured before the issuance of this new EU Type examination certificate according to the Regulation (EU) 2016/425.

This is PPE of category III, subject to regular checks in accordance with article 19 of the European PPE Regulation. In agreement with the manufacturer's choice audits of the production process shall be carried out to assess the Conformity of type (Module D). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31 Dec 2019 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 10158.

Issued by Centexbel, Notified Body 0493^(*), in Ghent, on 29 Mar 2018


Inge De Witte
Certification Manager
Attached: 1 Annex

^{*}Recognized by FPS Economy (Federal Public Services)