

EU and UK Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425



This EU Declaration of conformity refers to the following products:

Product name	Model	Classification	Batch No.
Chemical Protective Clothing(Partial Body)	ZIG1255A&ZIG1255B (ME-8024,ME-8025,ME-8026)	Type PB[6] Type PB[6]-B	

The Manufacturer's name and address is as follows:

Name	Wuhan Zonsen Medical Products Co., Ltd.
Address	No 8 Jinchao Road, Zhucheng Street, Xinzhou District, Wuhan, Hubei, China.

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

Detailed description of the PPE to allow traceability/identification of the PPE.

Guardwe Isolation Gown models ZIG1255A & ZIG1255B(single use):. Manufactured from a white polypropylene nonwoven laminated with a yellow polyethylene film(42gsm), with welded shoulder and sleeve seams. The gown has a bound neck opening with rear neck ties, a waist tie (welded) and is available with either elasticated or knitted cuffs. Available in seven nominal sizes:S- XXXXL.

The article identified in product category is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425, PPE Regulation 2016/425 as brought into UK law and amended. References to the relevant harmonized 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:

Type PB [6]: EN 13034:2005+A1:2009, EN ISO 13688:2013,
Types PB [6]-B: EN 14126:2003/AC:2004, EN 14325:2018

SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland (NB 0598) performed the EU Type Examination (Module B) and issued the Type Examination Certificate as follows:

No.	EU Type Examination (Module B) Certificate Number
1	0598/PPE/22/3219 Issue 1

SGS United Kingdom Limited, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, United Kingdom Approved body number 0120 performed the UK type-examination (Module B) and issued the UK type-examination certificate as follows:

No.	UK Type Examination (Module B) Certificate Number
1	0120/PPE/220703 Issue 1

The PPE is subject to the conformity assessment procedure conformity to type based on quality assurance of the production process (Module D) under surveillance of the notified body SGS Fimko Oy, Notified Body No. 0598 and SGS United Kingdom Limited, Approved Body No.0120.

Signature: 
Position: General Manger

Date: 2025-04-09

Company stamp: 