

EU Declaration of Conformity

Regulation (EU) 2016/425

1. This EU Declaration of conformity refers to the following products:

Product Name	Model	Classification/Type	Reference Number
Disposable Protective Coverall Full Protection (Type 5-B/6-B)	ENM - 102	CAT III	1020000S
			1020000M
			1020000L
			1020000XL
			1020002XL
			1020003XL

2. Manufacturer's name and address is as below:

Name	En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş.
Adress	SARAY MAH. GIDACILAR CAD. NO: 18 KAHRAMANKAZAN/ ANKARA

3. The Conformity assessment according to the essential requirements has been done by Eusepal according to

EU Community
Legislation

Personal Protective Equipment (PPE) Regulation (EU) 2016/425 Annex VII in connection with
Annex V (Module C2 EU Type Examination Certification- Certification SATRA Technology

Europe Limited, Notified Body Number: CE 2777

Certificate No.: 2163 - PPE -1424 Issued date: 28.04.2021

Harmonised
standart:

TS EN ISO 13688 : 2013 This International Standard specifies general performance requirements for ergonomics, innocuousness, size designation, ageing, compatibility and marking of protective clothing and the information to be supplied by the manufacturer with the protective clothing.

EN 13034:2005+A1:2009 - Protective clothing against liquid chemicals (Type 6)

ISO 13982-1:2004+A1:2010 – Protective clothing against solid particulates (Type 5),

EN 14126:2003/A:2004 Protective clothing. Performance requirements and tests methods for protective clothing against infective agents. This European Standard specifies requirements and test methods for reusable and limited use protective clothing providing protection against infective agents. Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions are not covered by the scope of this standard.

In cooperation with:

Notified Body

Satra Technology Europe Limited.

: 2777

This declaration is valid
until :

This certificate is initially issued on 28.04.2021 and will be valid for
1 years from the issue date.

Place and date of issue: Ankara/TURKEY

Date: 28.04.2021

Company Sign:

EN ECZA DEPOSU İLAÇ MEDİKAL
ÖZEL SAĞLIK HİZM. A.Ş.

EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ
İNŞAAT TAAHHÜT TİCARET ANONİM ŞİRKETİ
Adres Atatürk Mah. 31010044 - Kızılay Apt. No: 9/B Mezipli MERSİN
Adres No: 1294300476 İstiklal V.D.: 3350707675
MERSİN NO: 03350707675/00001 TİC. SİCİL NO: 51525
Tel: 0324 357 56 44 Fax: 0324 357 58 44



PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Issued to:

En Ezca Deposu İlaç Medikal
Özel Sag. Hiz. Ins. Taah. Tic. A.S.
Atatürk Mah. 31043 Sokak
Kubat Apt. No: 8/B Mezitli
Mersin
Turkey

This is to certify that the following products tested under SATRA reports referenced: STE0311168 & SPC0311442/2114 have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2163-PPE-1424	ENMED Protective Coverall Model ENM-102	Protective coverall Manufactured from laminated polypropylene non- woven fabric with hood inside overlocked seams, elastic cuff, ankle and waist zipper and zipper flap	EN ISO 13688:2013 EN ISO 13982-1:2004/A1:2010 Type 5 EN 13034:2005+A1:2009 Type 6 EN 14126:2003/AC:2004 Type 5-B Type 6-B

Dated: 28th April 2021

This certificate is
valid until: April 2022

Signed By (Alan Weston)

For and on behalf of SATRA Technology
Europe Limited



The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)

Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1424

En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş.
Atatürk Mah. 31043 Sk. Kubat Apt. No: 8/B Mezitli, Mersin / TURKEY

Manufacturing Site:

Karaduvar Mh. Serbest Bölge 18. Cad. Dışkapı No: 9 İç Kapı No: Z1 Akdeniz Mersin / TURKEY

It is certified that the manufacturer's technical file (Dated 01.07.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment

Brand Name: ENMED Protective Coveralls, **Model:** ENM-102

Protective coverall manufactured from laminated polypropylene non-woven fabric with hood, inside overlock seams, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

The following harmonised standards have been applied:

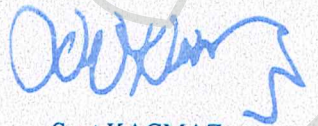
- EN ISO 13688:2013**, (General requirements for protective clothing)
- EN ISO 13982-1:2004/A1:2010**, (Chemical protective clothing providing protection to the full body against airborne solid particulates) Type 5, limited wear life clothing,
- EN 13034:2005+A1:2009**, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 6, limited wear life clothing,
- EN 14126:2003/AC:2004**, (Protective clothing against infective agents) for Type 5-B, 6-B.

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with the below requirements:

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **08/09/2020** and will be valid for 5 years from the issue date.




Suat KACMAZ
UNIVERSAL CERTIFICATION
Director





ENM-102 DISPOSABLE PROTECTIVE COVERALL- TYPE 5-B/6-B



**Excellent protection.
Elasticated waist and ankles.
Elasticated hood.
Two-way zipper.**

ENM-102 Protective Coverall TYPE 5-B/6-B (NON-STERILE) is designed to help protect against: hazardous dusts (Type 5) and light liquid splashes (Type 6).

Specification

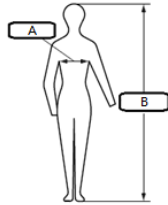
Material	:	Multilayer SMS Fabric Laminated	Fabric Weight	:	55 GSM
Zipper	:	Metal/ Nylon/ Polyester Braid	Elastic	:	Neoprene Rubber Latex Free
			Thread	:	Polyester

ENM-102

DISPOSABLE PROTECTIVE COVERALL- TYPE 5-B/6-B

Sizing

Size	Height(B)	Chest(A)
S	189 cm	56 cm
M	194 cm	60 cm
L	199 cm	64 cm
XL	204 cm	68 cm
2XL	212 cm	72 cm
3XL	221 cm	76 cm



Storage and Disposal

- Store in dry, clean conditions in original packaging, away from direct sunlight, sources of high temperature, and solvent vapours
- Store within the temperature range -5°C to +45°C and with relative humidity below min %40 max80% Rh.
- Expected shelf life is five years from date of manufacture when stored as stated
- Replace garments if damaged, heavily contaminated or in accordance with local work practice or regulations
- Handle and dispose of contaminated garments with care and in accordance with applicable regulations.
- CE approved PPE Directive (EU) 2016/425, Category III
- Certification SATRA Technology Europe Limited, Notified Body Number: CE 2777

Comfort and Protection



Liquid Protection
Type 6-B Light Liquid Splashes
EN13034:2005 + A1:2009



Dust Protection
Type 5- Solid Airborne Particulates
EN ISO 13982-1:2004+A1:2010



Biohazard
Type 5-B & 6-B - Body Protection
EN 14126:2003



CAT III
EN ISO 13982-1:2004+A1:2010



DO NOT REUSE



DO NOT BLEACH



DO NOT IRON



CAUTION



FLAMMABLE
KEEP AWAY FROM
SPARKS OF
FLAMES



CONSULT
INSTRUCTIONS
FOR USE



DO NOT WASH
LAUNDERING
IMPACTS UPON
PROTECTIVE



DO NOT
MACHINE DRY

Warnings and Limitations

Before use read and understand all user instructions and be sure that the product is suitable for the application and fitted correctly. Product must never be altered or modified. Prior to use inspect the clothing for any damage that could affect its protective function. Replace any damaged clothing. Care should be taken when removing contaminated garments, so as not to contaminate the user with any hazardous substances. If garments are contaminated, then decontamination procedures should be followed prior to removal of the garment. The wearing of chemical protective clothing may cause heat stress if appropriate consideration is not given to the workplace environment. Appropriate under garments should be considered to minimize heat stress or damage your garment.

Do not use for:

Contact with heavy oils, sparks or flame, or combustible liquids; Environments with high mechanical risks (abrasions, tears, cuts); Contact with hazardous substances beyond Type 5-B/6-B certification; Environments with conditions of excessive heat.

ENM-102 DISPOSABLE PROTECTIVE COVERALL- TYPE 5-B/6-B

Specification Sheet | Protective Coverall

Applications and Performance

Non-Hazardous Particulates	Yes
Non-Hazardous Liquid Splash	Yes
Non-Hazardous Liquid Spray	Yes
Liquid Continuous	No
Contact/ Immersion	No
Gases and Vapours	No
Hazardous Dusts & Fibres	Yes
Hazardous Liquid Splash	Yes, if chemical is compatible with suit material
Hazardous Liquid Spray	Yes, if chemical is compatible with suit material
Acids/Alkalis	Yes, if chemical is compatible with suit material
Organic Solvents	Yes, if chemical is compatible with suit material

User Guide



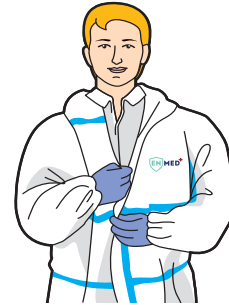
Select appropriate coverall and read User Instruction.



Remove shoes and secure trousers into socks. Step into legs of coverall and place coverall over safety boots.



Pull coverall towards arms and shoulders.



Pull zipper halfway up. Put on face mask (or respirator) and goggles. Pull hood over as head coverings. Cover sleeves over gloves.

Important Notice

**Compatible with ANSI/ISEA 101-2014

This guide is only an outline. It should not be used as the only means for selecting protective clothing. Before using any protective clothing, the wearer must read and understand the user instructions for each product. Specific country legislation must be observed. If in doubt, contact a safety professional. Selection of the most appropriate PPE will depend on the particular situation and should only be made by a competent person knowledgeable of the actual working conditions and the limitations of PPE. Final determination as to the suitability of these products for a particular situation is the employer's responsibility. This information is subject to revision at any time. Always read and follow all User Instructions supplied with your Coverall in order to ensure correct operation. If you have questions contact ENMED Technical Service.

LIMITATION OF LIABILITY: Except as provided above, ENMED shall not be liable or responsible for any loss or damage, whether direct, indirect, incidental, special or consequential arising out of the sale, use or misuse of ENMED products, or the user's inability to use such products.