



NATIONAL INSTITUTE OF RESEARCH -
DEVELOPMENT FOR OCCUPATIONAL SAFETY
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Certification Body ICSPM-CS
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Notified Body: NB 2756

acreditat pentru
CERTIFICARE



SR EN ISO CEI 17065:2013
CERTIFICAT DE ACREDITARE
ON 092

EU TYPE – EXAMINATION CERTIFICATE No. 3545/EIP/28.05.2020

1. This certificat is issued for:

- **Type (model) of PPE:** Single use coverall, Model ZC3B-53L
- **Type designation:** «ZC3B-53L»
- **PPE category:** Category II PPE (PPE that is neither category I, nor category III) - Equipment providing general body protection (clothing), against substances and mixtures which are hazardous to health
- **Manufacturer:** BM PORTAVITA S.R.L., MD-2059, Strada Petricani 17/22, Chișinău, Republica Moldova , C.U.I.: 1002600030242

2. General references and applied procedure for conformity assessment/applied certification scheme:
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)"

3. Conclusions of the conformity assesment: Following the carrying of the conformity assessment, the notified body atests that:

- 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 and specified in the annex of this certificate
- The PPE type complies with the applicable essential health and safety requirements set out in Annex II of the Regulation (EU) 2016/425, which apply to it, taking into account the intended use claimed by the manufacturer and specified in the annex of this certificate
- PPE conforms to the following harmonised standards: SR EN 13034+A1:2010 (EN 13034:2005+A1:2009) – Type 6, SR EN ISO 13688:2013 (EN ISO 13688:2013)

4. Valability of the certification:

- Date of expiry of the certificate: 28.05.2025.
- This certificate is valid only with Annex, as an integrated part of the former.

**PRESIDENT
NOTIFIED BODY**

dr. eng. Doru Costin DARABONT



HEAD OF PPE CERTIFICATION UNIT

dr. eng. Nicoleta CRĂCIUN

ANNEX

1. Designation of the model

Single use coverall, Model ZC3B-53L

2. Product description

The coverall is made of non-woven Spunbond laminated with PE film, with a mass of about 53 g / m² made of 100% polypropylene. The coverall is with hood fitted with elastic around the face, zipper closure system covered with slit; kimono sleeves finished with elastic for adjustment on the wrist and trousers have attached overshoes (boots) that at the end. All joints are made by sewing with 100% polyester sewing thread and sealed with heat-sealed tape.

The model is made in the following sizes: M; L; XL; XXL; XXXL; 4XL, with construction dimensions made explicit in DT ZC3B-53L / 2020, according to the requirements of EN ISO 13688.

This document also applies to variants of the basic model, differentiated by colors, comfort or functional elements (eg. style for application of the sleeves, number of parts for back side, chests or sleeves, number and positioning of pockets covered with flaps, specific inscriptions, applied embroidery)



- **Materials:** Non-woven Spunbond laminated with PE film, with a mass of about 53 g / m² made of 100% polypropylene, zippers, elastic, seam sealing tape

- **Location for the manufacturing of the PPE:** BM PORTAVITA S.R.L., MD-2059, Strada Petricani 17/22, Chişinău, Republica Moldova

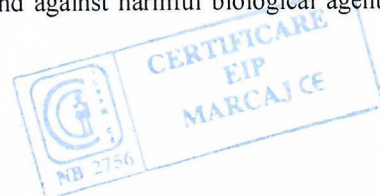
3. **Intended use:** protective clothing which ensures limited protection of the whole body against chemicals, when it is not necessary a total barrier against the permeation of liquids (at the molecular level) - acids and bases of low concentration, hydrocarbons, alcohols - in case of possible exposures to light sprays, liquid aerosols, accidental spraying with small quantities and at low pressure, when the risk is estimated to be low and the wearer is able to take quickly appropriate measures in case of contamination of his clothing, protection against superficial mechanical injuries (abrasion, hanging); to be used in normal environments without potentially explosive atmosphere and without risk of contact with open flame

4. References for the conformity assessment/certification:

4.1 **Procedures of the notified body:** general procedure: «PPE conformity assessment applying the procedure “EU type-examination (Module B)” referred to in Regulation (EU) 2016/425, PG EIP R MODUL B and specific procedure for protective clothing, PSC EIP R- 05.

4.2 **Health and safety requirements to be met by the model:** set out in Annex II of the Regulation (EU) 2016/425, which 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 user impediment); 1.3. (Comfort and effectiveness); 1.3.1 (Adaptation of PPE to user morphology); 1.3.2. (. Lightness and strength); 1.4 (Manufacturer's instructions and information);
- ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE: 2.2. (PPE 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 or indirectly 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).



4.3 Standards and other specifications

- a) **harmonised standards** which give the presumption of conformity with the essential health and safety requirements to be applied to the product
- SR EN 13034+A1:2010 (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] equipment)»
 - SR EN ISO 13688:2013 (EN ISO 13688:2013) «Protective clothing - General requirements (ISO 13688:2013)»
- b) **other standards and specifications taken into consideration** – connexed standards or un-harmonized standards:
- SR EN 340:2004 (EN 340:2003) « Protective clothing-General requirements» - standard canceled, but connected to the requirements standards
 - SR EN 14325:2004 (EN 14325:2004) « Protective clothing against chemicals — Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages» - for classification of the mechanical characteristics.

5. Information related to the carried out type testings and examination

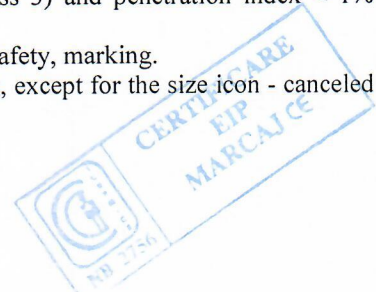
- **Code of technical file at the notified body de certificare:** EIP 5/1685
- **Language of technical file submitted to examination:** Romanian.
- **Reference model:** -
- **Conformity assessment activities:** The conformity assessment has been carried out by a full procedure
- **Technical file submitted to examination:** code DT ZC3B-53L/2020 + manufacturer's instruction and information file code F.I. ZC3B-53L/2020
- **Test reports and certificate s used in evaluation of conformity:**
 - Test Report Nr 5769 from 26.05.2020 issued by Laboratory mIP of INCDPM
 - OEKO-TEX Standard 100 certificate No. 14.HTR.48982 from 28.06.2019 issued by Hohenstein Textile Testing Institute GmbH & Co, Germania (material)

- **Evaluation report:** RE/EIP/2375/28.05.2020 (confidential)




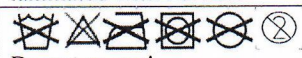
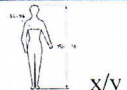
6. Conclusion of the EU type examination

The technical design of the PPE model "Single use coverall, Model ZC3B-53L" meets the requirements of the Regulation (EU) 2016/425 and the essential health and safety requirements corresponding to the intended use. The model submitted to the conformity assessment, manufactured according to the technical file, meets the specifications included in the technical file and the following standards:

- **SR EN 13034+A1:2010 (EN 13034:2005+A1:2009)** - all the requirements for chemical protective clothing, made of textile fabric, covering the entire body, Type 6, having performance levels within the following classes according to SR EN 14325:2004 (EN 14325:2004):
 - abrasion resistance: >1500 cycles (class 5);
 - tear resistance - trapezoidal test specimen (method ISO 9073-4): > 20 N for both directions (class 2);
 - tensile strength: > 30 N for both directions (class 1);
 - puncture resistance: >5 N (class 1);
 - seams resistance: > 75 N for any type of seam (class 3)
 - resistance to splashing with sulfuric acid 30%: repellency index > 95% (class 3) and penetration index < 1% (class 3);
 - resistance to splashing with sodium hydroxide 10%: repellency index > 90% (class 2) and penetration index < 1% (class 3)
 - resistance to splashing with o-xylene: repellency index > 95% (class 3) and penetration index < 1% (class 3)
 - resistance to splashing with butan-1-ol: repellency index > 95% (class 3) and penetration index < 1% (class 3).
- **SR EN ISO 13688:2013 (EN ISO 13688:2013)** - ergonomic requirements, safety, marking.
- **SR EN 340:2004 (EN 340:2003)** - ergonomic requirements, safety, marking, except for the size icon - canceled standard, as a standard related to type standards.



The permanent marking on each item shall be conform to the following model (minimum):

| Marking symbols | Significance | Place to be applied |
|---|--|---------------------|
| BM PORTAVITA SRL, Strada Petricani 17/22, Chişinău, Republica Moldova email: info@portavita.md | Identification of manufacturer | On a sewed label |
| ZC3B-53L | Manufacturer's type/model designation | |
|  | CE marking | |
| EN 13034:2005 +A1:2009  Type 6 | Number and year of publication of the complied standard, regarding clothing against chemicals + "Protection against chemicals" pictogram (ISO 7000-2414) + protection type - type 6 (covering the whole body) or type PB [6] (covering body parts) | |
|  | Attention for reading the instruction and information file | |
| Lot | Lot (unique code or month/ year of manufacture or year of manufacture) | |
| Composition: 100% polypropylene laminated with PE film | Composition of execution materials | |
|  Do not re-use! | Pictograme de întreţinere + warning phrase for single use PPE | |
|  x/y | Size pictogram with indication of bust circumference and body height + size in the usual Romanian system (X = bust circumference / Y = code indicating the stature) | |

Specific condition for use of EU type examination certificate and for the references to it and to the notified body:

1. The EU type-examination certificate shall be kept by the manufacturer together with the technical documentation which has been the subject of the EU type-examination and with copies of the EU declaration of conformity for 10 years after the last placing on the market of an individual PPE component.
2. The body allows the manufacturer to make references to the certificate and the notified body in the EU declaration of conformity and in the instruction and information sheet provided with the PPE when, following internal production control, it has been ensured that the manufactured PPE conforms to the approved model.
3. The manufacturer shall notify the notified body of any modification of raw materials, manufacturing technology, technical documentation or other documents accompanying the delivered PPE items, that have been made to those subjected to the EU type examination, otherwise the issued certificate shall lose its validity.
4. The EU type-examination certificate may be suspended, withdrawn or restricted by the notified body where there is information that, for reasons not known at the time of issue of the certificate, the verified PPE model no longer meets the requirements of the technical regulation.
5. On expiry of the validity of the EU-type-examination certificate or on the issue of any other document by which the body suspends, withdraws or restricts its use, the manufacturer shall cease to place on the market PPE.

