OXYLINE Sp. z o.o., 95-200 Pabianice, ul. Piłsudskiego 23
Sąd Rejonowy dla Łodzi-Śródmieścia, nr KRS: 0000299083, NIP: PL7692143818, REGON: 100482830
Nr konta: Bank Millennium S.A., 26 1160 2202 0000 0001 0694 2836, Kapitał zakładowy: 2 325 000,00 zł
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EU DECLARATION OF CONFORMITY

1. Medical device and personal protective equipment: **Protective coverall Oxychem C210**

2. Code Basic UDI-DI : **590737757OxyChemC210HU**

3. Registration number SRN, name and address of the manufacturer:
PL-MF-000012747, Oxyline Sp. z o.o., ul. Piłsudskiego 23, 95-200 Pabianice, POLAND.

4. This declaration of conformity is issued under the sole responsibility of the manufacturer:
Oxyline Sp. z o.o., ul. Piłsudskiego 23, 95-200 Pabianice, POLAND.

5. The object of the declaration is a protective coverall **OxyChem C210** in Class I and Rule 1 for medical devices and in category III Type 5, 6 as personal protective equipment.

6. The subject matter of the declaration described in section 5 . complies with the relevant requirements of EU harmonisation legislation:
   a. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)
   b. 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 (Text with EEA relevance).

7. In addition, protective coverall **OxyChem C210** meets the minimum requirements specified by harmonized product standards:
   a. Medical
   - EN ISO 15223-1:2021 -- Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements.
   - EN ISO 20417:2021 -- Medical devices — Information to be supplied by the manufacturer.
   - EN ISO 14971:2019 -- Medical devices. Application of Risk management for medical devices.

   b. PPE
   - EN ISO 13688: 2013 - Protective clothing -- General 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] clothing).
   - EN ISO 13982-1: 2004 + A1: 2010 -- Protective clothing against solid particulates -- Part 1: Performance requirements for clothing providing protection to the full body against airborne solid chemical particulates (Type 5 clothing).
   - EN 1073-2: 2002 -- Protective clothing against radioactive contamination -- Part 2: Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination.
   - EN 1149-5: 2018 -- Protective clothing - Electrostatic properties - Part 5: Material performance and design requirement.
   - EN 14126: 2003 + AC: 2004 - Protective clothing -- Requirements and test methods for protective clothing against infective agents.

8. Notified body **Centro Tessile Cotoniero e Abbigliamento S.p.A. – Centrocot, p.zza Sant'Anna 2, 21052 Busto Arsizio, Italy, Notified Body N° 0624** conducted the EU test (module B) and issued EU type examination certificate No. **CE 1080240313 - 00 – 00**

9. Where appropriate, PPE is subject to a type-conformity assessment procedure based on quality assurance of the production process (module D), under the supervision of notified bodies **Centro Tessile Cotoniero e Abbigliamento S.p.A. – Centrocot, p.zza Sant'Anna 2, 21052 Busto Arsizio, Italy, Notified Body N° 0624**

Signed: Oxyline Sp. z o.o.

Pabianice, 05 May 2024

Arkadiusz Dziębowski

CEO

EN

OxyChem C210

Protection Coverall, Cat. III, Type 5, 6. Medical product Class I

Certification

Type 6 - Protective clothing against liquid chemicals - low-pressure splashes	**Type 5** - Protective clothing against particulates	Protective clothing against radioactive contamination	Electrostatic properties	Protection against infectious agents	Protective clothing - General requirements
EN 13034:2005 +A1:2009	EN ISO 13982-1:2004 +A1:2010	EN 1073-2:2002	EN 1149-5:2018	EN 14126:2003 +AC:2004	EN ISO 13688:2013

Lightweight and tough

The **OxyChem C210** protective suit is designed for protection in
It is designed to provide protection in areas exposed to infectious materials and provides limited type 5/6 anti-chemical protection. It is made of non-woven fabric laminated with a microporous film **(MPFL)** of 63g/m^2 +/- 2g/m^2. Outer layer: polyethylene film. Inner layer: polypropylene fibres. Non-woven fabric **(MPFL)** is resistant to permeation infectious agents. **OxyChem C210** also provides protection against radioactive contamination and has anti-electrostatic properties. Its construction is designed to provide the wearer with the highest level of safety, ergonomics and comfort during work.

Properties

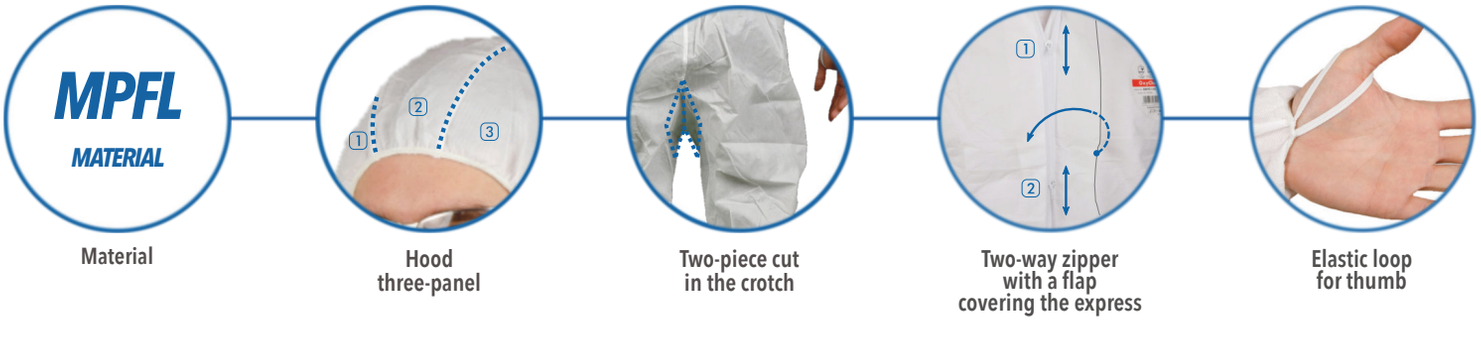
- Spunbond fabric laminated with microporous film **(MPFL)**, 63g/m^2 +/- 2g/m^2
- Three-panel hood
- Two-way zip with fabric patch
- Two-piece crotch cut
- Elastic cuffs, legs, waist and hood
- Elastic thumb loop
- Durable overlock seams on the inside

Application for jobs

- When working with asbestos
- When painting and spray-painting
- When laying insulation and earthworks
- When working on water supply systems, in sewers
- In the pharmaceutical industry
- When working with resin
- Machine maintenance
- During light spraying work, e.g. in agriculture
- In the automotive industry
- Grinding and polishing
- In the pharmaceutical and medical industries

Packing

The suit is individually wrapped in a sealed foil package.
Quantity in a carton - 50 pcs.
Quantity of overalls on a pallet - 1000 pcs.
Quantity of cartons on a pallet - 20 pcs.
Gross weight of cardboard - 12,8 kg
Dimensions of the cardboard - 48 cm x 28 cm x 54 cm



Material | Hood three-panel | Two-piece cut in the crotch | Two-way zipper with a flap covering the express | Elastic loop for thumb

Technical parameters

Type of protection obtained according to EN 14126 (Protective clothing - Requirements and test methods for protective clothing against infectious agents) - Performance levels.

Standard	Title	Retrieved from type protection
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] of clothing)	**Type 6B**
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)	**Type 5B**

Performed examinations and tests in accordance with EN 14126 (test for protection against infectious agents):

Standard test	Result obtained	Classification by result
Pressure test, resistance to penetration of blood and body fluids with synthetic blood (EN ISO 16603 + EN 14126 par. 4.1.4.1)	**20kPa**	**Class 6**
Resistance to pathogen penetration from blood using bacteriophage (Fag Fi-X174) (resistance to viral penetration) (EN ISO 16604 + EN 14126 par. 4.1.4.1)	**> 75 min**	**Class 6**
Resistance to bacterial penetration (EN ISO 22610 + 14126 par. 4.1.4.2)		
Resistance to penetration of biologically contaminated aerosols (EN ISO 22611 + EN 14126 par. 4.1.4.3)	**Log10 CFU > 5**	**Class 3**
Resistance to penetration of contaminated dust (EN ISO 22612 + 14126 par. 4.1.4.4)	**Log10 CFU < 1**	**Class 3**

Performed examinations and tests in accordance with EN 1073-2 (protection against contamination with radioactive particles):

Standard test	Result obtained	Classification by result
Total internal leakage (EN ISO 13982-2 + EN 1073-2)	**TILE < 3% TILA < 2%**	**Class 2**

Parameters relating to the strength of the garment (physical properties)

Standard test	Result obtained	Classification by result
Determination of resistance to abrasion of materials (EN 530 met. 2 + EN 14325 par. 4.4.1 + EN 13034 par. 4.1)	**> 1000**	**Class 4**
Determination of resistance to flexural fracture (EN ISO 7854 met. B + EN 14325 par. 4.5 + EN ISO 13982-1 par. 4.1)	**> 100 000**	**Class 4**
Determination of trapezoidal tearing strength (EN ISO 9073-4 + EN 14325 par. 4.7 + EN 13034 par. 4.1)	**Longitudinal > 60 Transverse > 40**	**Class 4/3**
Determination of resistance to push-out (EN ISO 13938-1 + EC 1 +EN 14126 par. 4.1.2)	**> 320**	**Class 4**
Tensile strength and elongation. Strip method (EN ISO 13934-1 + EN 14325 par. 4.9 + 13034 par. 4.1)	**Longitudinal > 100 Transverse > 60**	**Class 3/2**
Puncture resistance of materials (EN 863 + 1073-2 par. 4.2)	**> 50**	**Class 3**
Electrostatic properties test Surface resistivity (EN 1149-1 + EN 1149-5 par. 4.2.1)	**< 2,5 x 10^9 Ω**	
Seam strength (max. breaking load) using the grab method (EN 13935-2 + EN 14325 para. 5.5 + EN ISO 13982-1 para. 4.2.2)	**> 100**	**Class 3**
Flammability tests (ignition and flammability) (13274-4 met 3 + EN 1073-2 par. 4.2)		**Test passed**

Examinations and tests according to EN 13034 (protection against liquid chemicals)

Standard test	Result obtained
Test of resistance against chemicals (EN ISO EN ISO 6530 + EN 14325 par. 4.12 and 4.13 + EN 13034 par 4.1)	**H_2SO_4 (30%) < 1 NaOH (10%) < 1 o-Ksylen < 1 N-butanol < 1**
Resistance to penetration by sprayed liquid (Spray test) (EN ISO 17491-4 + EN 14605 par. 4.3.4)	**Test passed**

Additional research:

Standard test	Result obtained
Determination of pH of aqueous extracts (mean PH value of extracts 20 and 30) (EN ISO 3071 + EN ISO 13688 para. 4.2)	**3,5 > pH > 9,5**
Cytotoxicity tests (Mean % cell survival after incubation) (EN ISO 10993-5)	**94.47% - is not cytotoxic**
Dermatological test (Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products) (irritation index X_{mn})	**Non-irritant product X_{mn} = 0**

Assessment of Declared Product Properties - Protective Suit OxyChem C210/C310 (by J.S. Hamilton Poland Sp. z O.O. - No. 99014/21/CGDA of 22.03.2021)

On the basis of the results of the conducted performance test, the properties of the product KOMBINEZON OXYCHEM C210/C310 declared by the manufacturer were evaluated as follows:

The product allows for easy dressing and removal.	**100% positive responses**
The product is convenient to use.	**96% positive responses**
The product does not put undue pressure on the skin (welts).	**92% positive responses**
The product does not cause reddening at the contact with the skin.	**92% positive responses**
The product provides good thermal comfort while working.	**100% positive responses**
The product is airtight.	**100% positive responses**
The product adheres well at the cuffs, legs, hood.	**96% positive responses**
The product allows freedom of movement while working.	**100% positive responses**

In addition, it was assessed:

Proper application of the product.	**100% positive responses**
Suitable product texture.	**96% positive responses**
Overall product rating.	**84% positive responses**
Intention to purchase the product.	**88% positive responses**
Willingness to recommend the product to a friend.	**88% positive responses**

EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer.
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.

The EU Declaration of Conformity is available at: https://www.oxyline.eu/deklaracje-kombinezony.html

The OxyChem C210 one-piece protective suit is a Class I, non-sterile medical device which complies with the requirements of Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.) and complies with the Medical Devices Act of 20.05.2010. It is also a Category III PPE in accordance with 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 (Text with EEA relevance). Product designed and placed on the market in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 and Regulation EU 2016/425 of the European Parliament and of the Council of 9 March 2016.

Sizing	S	M	L	XL	XXL	XXXL
Height	164 - 170	170 - 176	176 - 182	182 - 188	189 - 194	194 - 200
Chest	84 - 92	92 - 100	100 - 108	108 - 117	116 - 124	124 - 132

Exposure to certain chemicals or to high concentrations may require higher protective properties through the suit's material or construction properties. Such areas may be protected by suit types 1,2,3 or 4.