

19 March 2020

**COMMUNICATION No. 1**

**on testing and conformity assessment of respiratory protective equipment,  
protective clothing and eye and face protection in the context of prevention  
measures related to the COVID-19 pandemic**

In connection with the COVID-19 pandemic, please note that the Central Institute for Occupational Protection - National Research Institute (CIOP-PIB) is competent to perform the testing of respiratory protective equipment, protective clothing and eye and face protection in the following areas:

**A. TESTING OF FILTERING HALF-MASKS**

Tests of filtering half masks are carried out in accordance with **EN 149:2001 + A1:2009** (Polish version: **PN-EN 149+A1:2010**) *Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking*. This standard is harmonised with the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 which governs the placing of personal protective equipment on the European Union market.

The scope of tests carried out by CIOP-PIB refers in particular to the following types of half masks:

- **FFP1** (P1-penetration of aerosol particles at the level of 20%, which means that the effectiveness of such half-masks in retaining harmful aerosol particles of the size from 300 nm is 80%),
- **FFP2** (P2-penetration of aerosol particles at the level of 6%, which means that the effectiveness of such half-masks in retaining harmful aerosol particles of the size from 300 nm is 94%),

- **FFP3** (P3-penetration of aerosol particles at the level of 1%, which means that the effectiveness of such half-masks in retaining harmful aerosol particles of the size from 300 nm is 99%, and thus ensures the highest tightness in this class of filtering half-masks).

In order to perform the full range of tests for compliance with EN 149:2001 + A1:2009, 50 half-masks are needed for one type of mask. The standard test deadline is 25 days from the moment of delivering the samples for testing, but with some justified simplification of the procedures for preparation and conditioning of the test samples it is possible to perform the test within 14 days.

**Apart from the above mentioned standard methodology of half masks testing, CIOP-PIB has also the possibility to perform additional tests of filtration efficiency against nanoparticles in the range of 7-270 nm, which gives the possibility to assess to what extent the half mask retains particles of the size of SARS-CoV-2 viruses (i.e. 60 - 140 nm).**

It is very important for the protection efficiency of filtering half-masks to ensure that they are properly fitted by the individual user. During standard laboratory tests of respiratory protective equipment (filtering half-masks and half-masks with filters), we conduct fit (tightness) assessment with the participation of 10 volunteers whose face dimensions are defined in **EN 149:2001 + A1:2009** based on measurements of the Central European population. The leakage test referred to in the standard as "Total inward leakage" is carried out in an atmosphere of aerosol spray of sodium chloride particles with an average particle diameter of 600 nm and a dimensional distribution including particles of the size of the virus. The compliance of respiratory protective equipment with this parameter confirms that it can be tightly fitted by the user with typical face dimensions.

The correct way for an individual user to put on, fit and check tightness of the half-mask is described in a separate instruction.

If necessary, we can undertake the training of healthcare professionals representatives from designated hospitals and other units.

## **B. TESTING OF HALF MASKS WITH REPLACEABLE FILTERS**

Respiratory protective equipment against harmful aerosols, including bioaerosols, is a half mask made of rubber or silicone and completed with filters of protection class 1, 2 or 3, respectively (marked as P1, P2, P3 filter). The filtration efficiency of P1 filters is 80% (20%

penetration of aerosol particles with average diameter from 300 nm), P2 filters - 94% (6% penetration of aerosol particles with average diameter from 300 nm), P3 filters - 99.95% (0.05% penetration of aerosol particles with average diameter from 300 nm).

The basic types of filters used in these half masks are as follows:

- **capsule filters without connectors** made of loose fibers or systems of filtering non-woven closed in a container with openings to allow for free flow of breathing air; require the use of connectors in face parts,
- **capsule filters with a connector** which most often contain the pleated fleece enclosed in a housing with an inlet on one side and a connector (threaded or bayonet) on the other,
- **non-capsule filters without connectors** consist of several layers of filtering non-woven, connected together on a perimeter. They require the use of a facepiece equipped with a connector to ensure a tight fit.
- **non-capsule filters with a connector** made of a system of filtering non-woven of various shapes (e.g. truncated cone, disks, tears); on one side they are equipped with a threaded or bayonet connector enabling connection with a half-mask.

All the above mentioned filters are tested in accordance with **EN 143:2000/A1:2006 (Polish version: PN EN 143:2000/A1:2006) Respiratory protective devices. Particle filters. Requirements, testing, marking.**

Half masks combined with P1, P2 and P3 filters shall meet the requirements of **EN 140:1998 (Polish version: PN EN 140:2001) Respiratory protective devices. Half masks and quarter masks. Requirements, testing, marking.**

At least 15 samples are needed for the testing of half masks with replaceable filters. The time required for full testing: 10 days from the date of delivery of samples.

To test only the filters, additional 20 sets are needed (a set is 2 filters for each half-mask). Testing time: 7 days from the date of delivering samples.

### **C. TESTING OF MEDICAL FACE MASKS**

The procedure for testing medical masks in accordance with **EN 14683:2019+AC Medical**

**face masks - Requirements and test methods** includes the following parameters that can be tested at CIOP-PIB:

1. bacterial filtration efficiency (BFE), with the use of *Staphylococcus aureus*,
2. microbiological cleanliness,
3. breathability (differential pressure),
4. biological compatibility in terms of:
  - (a) in vitro cytotoxicity assessment in accordance with the requirements of the standard PN-EN ISO 10993-5:2009,
  - (b) assessment of skin sensitisation according to PN-EN ISO 10993-10:2015-02 (Buehler method),
  - (c) assessment of skin irritation according to PN-EN ISO 10993-10:2015-02 (5-fold application).

The testing of the first three parameters mentioned above can be performed within 10 days from the date of delivery of samples. However, the bio-compatibility tests listed in point 4 under (a), (b) and (c) are long-term tests, and their duration is 10 weeks (cytotoxicity), 8 weeks (sensitisation) and 3-5 weeks (irritation) respectively.

#### **D. TESTING OF PROTECTIVE CLOTHING**

Clothing protecting against infective (biological) agents should meet the requirements of **PN-EN 14126:2005 Protective clothing. Performance requirements and test methods for protective clothing against infective agents** (equivalent to EN 14126:2003 and EN 14126:2003/AC:2004 standards). This standard is harmonised with the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 which governs the placing of personal protective equipment on the European Union market.

PN-EN 14126:2005 covers the requirements for resistance to penetration of infective agents and mechanical properties of clothing materials, the requirements for tightness of seams, separable and permanent connections in the clothing and the requirements for the whole garment (depending on the type of clothing). Similarly to every type of protective clothing, clothing protecting against biological agents should meet the general requirements of PN-EN ISO 13688:2013-12 (which implements EN ISO 13688:2013) in terms of harmlessness for the wearer and ergonomics in relation to the materials used in the clothing, as well as its construction, and also regulates the issues of maintenance of protective clothing, size symbols,

marking and instructions for use.

As regards the protective properties against penetration of infective agents, protective clothing against biological agents shall meet the requirements for resistance to penetration of: contaminated liquid under hydrostatic pressure, contaminated liquid aerosols, contaminated solid particles and contaminated particles through mechanical contact with contaminated liquids. Due to the particle size of the SARS- CoV-2 virus (0.125µm), clothing intended for protection against it shall, in particular, meet the requirements of section 4.1.4.1 of EN 14126:2005 in the highest possible class and consequently be tested according to ISO 16604, i.e. for resistance to the penetration of contaminated liquids under hydrostatic pressure.

In order to ensure the protection against SARS-CoV-2 virus, the design of protective clothing shall be at least type 4 in accordance with EN 14605:2005+A1:2009, which means that the clothing shall be resistant to the penetration of spray, i.e. the relevant tightness of the seams and joints.

For the testing protective clothing, 8 suits or 4 m of clothing material, 1 m of seam and 3 suits are needed.

The testing time at CIOP-PIB laboratory is 7 days. The time of testing in the microbiological laboratory Centexbel, which cooperates with CIOP-PIB, is about 4 weeks, with the possibility of speeding up the tests at an additional charge.

## **E. TESTING OF EYE AND FACE PROTECTION**

Eye and face protection, such as safety glasses, goggles and face shields are assessed in accordance with the requirements of the harmonised standard **EN 166:2001 (Polish version: PN-EN 166: 2005) Personal eye protection. Specifications**. The tests are carried out in accordance with the methods specified in harmonised standards:

- **EN 167:2001 (PN-EN 167:2005) Personal eye protection. Optical test methods,**
- **EN 168:2001 (PN-EN 168:2005) Personal eye-protection. Non-optical test methods.**

To protect against biological agents, eye and face protection should have a high level of tightness. This level is provided by protective goggles, the frame of which shall fit tightly to the face, and by face shields with additional elements ensuring direct adhesion of the shield to the face. The parameters relating to the tightness of eye and face protection are as follows:

- protection against liquid drops (marked with 3),

- protection against coarse dust particles (dust of particle size > 5 pm, protection marked with 4),
- protection against fine dust particles (aerosols, fumes and dusts of particle size < 5 pm, protection marked with K).

For the testing of goggles and eye and face shields 12 pieces of each type are needed. Testing time is 7 days from the date of delivery of samples.

## F. HAND PROTECTION

Gloves protecting against biological agents such as viruses, bacteria and fungi are classified as category III personal protective equipment under the Regulation (EU) 2016/425. Gloves for protection against viruses should meet the requirements of the following standards:

- **EN ISO 374-5:2016** (Polish version: **PN-EN ISO 374-5:2017-02**) **Protective gloves against dangerous chemicals and micro-organisms. Part 5: Terminology and performance requirements for micro-organisms risks,**
- **EN 420:2003+A1:2009** (Polish version: **PN-EN 420+A1:2012**) **Protective gloves. General requirements and test methods.**

In accordance with PN-EN ISO 374-5:2017-02 standard, gloves protecting against viruses are tested for:

- resistance to penetration using the method of leakage testing with air and water according to PN-EN 374-2:2015-04 (EN ISO 374-2:2014) Protective gloves against dangerous chemicals and microorganisms. Part 2: Determination of resistance to penetration
- protection against viruses - according to ISO 16604 test method (method B) using Phi-X174 bacteriophage (particle size of 27 nm). The gloves shall be free of detectable virus transmission (<1 PFU/ml bacteriophage in the titrant being determined),
- dimensions and dexterity of fingers according to the methods described in PN-EN 420+A1:2012.

The Phi-X174 bacteriophage test method has been developed to model the transmission of hepatitis B and C viruses and human immunodeficiency viruses transmitted in blood and other potentially infectious body fluids.

CIOP-PIB laboratory requires 5 pairs of gloves in all offered sizes for the testing of gloves

protecting against penetration of microorganisms according to PN-EN ISO 374-5:2017-02. The testing time is 4 days. For the testing of gloves protecting against penetration of microorganisms in accordance with PN-EN ISO 374-5:2017-02, CENTEXBEL laboratory requires 4 pairs of gloves. The testing time is 4 weeks.

## **TECHNICAL COMPETENCES OF CIOP-PIB**

The tests listed in points A, B, D, E and F are performed at CIOP-PIB in accordance with the procedures accredited by the Polish Centre for Accreditation (accreditation certificate no. AC 018) within the scope of CIOP-PIB's activities as EU Notified Body No. 1437 to conduct conformity assessment of personal protective equipment 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.

The tests listed in point C fall within the scope of Directive 93/42/EEC concerning medical devices, according to which the conformity assessment procedure for medical masks does not require the participation of a third party and so far these masks have not been referred to testing. The testing procedures are carried out in accordance with the requirements of EN 14683:2019+AC.

### **Authors:**

- Prof. Katarzyna Majchrzycka – Head of the Department of Personal Protective Equipment, e-mail: kamaj@ciop.lodz.pl, tel. +48 42 648 0221, mobile +48 601 42 44 06.
- Dr Małgorzata Pośniak, Head of the Department of Chemical, Biological and Aerosol Hazards; e-mail: mapos@ciop.pl, tel. +48 22 623 4662.
- Prof. Rafał L. Górny, Head of Laboratory of Biohazards, e-mail: ragor@ciop.pl, tel. +48 22 623 4677.

**Coordinator:** Dr Daniel Podgórski, Deputy director for management systems and certification, e-mail: dapod@ciop.pl, tel. +48 22 623 4602, mobile +48 601 33 09 28

