Personal protective equipment (*PPE*) requirements

half masks

Half masks shall comply with the following requirements:

1. compliance with the following standards:
   - PN-EN 140:2001/Ap1:2003 – Respiratory protective devices – Half masks and quarter masks – Requirements, testing, marking (or, respectively: EN 140:1998 EN 140:1998/AC:1999);
   - PN-EN 149+A1:2010 – Respiratory protective devices – Filtering half masks for protection against particles – Requirements, testing, marking (or, respectively: EN 149:2001+A1:2009)
2. Declaration of Conformity for compliance with the requirements of Regulation (EU) 2016/425
3. CE marking

   Half masks may comply with the requirements of NIOSH-42C FR84 standard (US) or GB2626-2006 (China) or AS/NZ 1716:2012 (Australia) or JMHLW – Notification 2014-2018 (Japan) – please read CIOP (Central Institute for Labour Protection) guidelines.

Goggles

Goggles (eye protection) shall comply with the following requirements:

1. compliance with the following standards:
   - PN-EN 167:2005 – Personal eye protection – Optical test methods (or, respectively: EN 167:2001);
   - PN-EN 168:2005 – Personal eye protection – Non-optical test methods (or, respectively: EN 168:2001)
2. Declaration of Conformity for compliance with the requirements of Regulation (EU) 2016/425
3. CE marking

gloves

Medical gloves shall comply with the following requirements:

1. compliance with the following standards:
   - PN-EN 455-1:2004 – Medical gloves for single use – Part 1: Requirements and testing for freedom from holes (or, respectively: EN 455-1:2000);
   - PN-EN 455-2+A2:2013-06 – Medical gloves for single use – Part 2: Requirements and testing for physical properties (or, respectively: EN 455-2:2009+A2:2013);
   - PN-EN 455-3:2007 – Medical gloves for single use – Part 3: Requirements and testing for biological evaluation (or, respectively: EN 455-3:2006)
   - PN-EN 455-4:2010 – Medical gloves for single use – Part 4: Requirements and testing for shelf life determination (or, respectively: EN 455-4:2009)
2. Declaration of Conformity for compliance with the requirements of Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures for medical devices (Journal of Laws, item 211) Declaration of Conformity for compliance with the requirements of Directive 93/42/EEC or Declaration of Conformity for compliance with the requirements of Regulation (EU) 2017/745
3. CE marking

In case of protective gloves it is necessary to comply with the PN-EN ISO 374-2:2020-03 standard Protective gloves against chemicals and micro-organisms — Part 2: Determination of resistance to penetration, or PN-EN ISO 374-1:2017-01, which is harmonised with Regulation 2016/425. Declaration of Conformity for compliance with the essential requirements of Regulation (EU) 2016/425 is also required.

disinfection liquids

Depending on the group to which a given disinfectant has been classified (determined by its intended use)

Disinfectants, as medical devices, shall comply with the following:

1. compliance with the following standards:
    - PN-EN 13624:2006 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants intended for instruments used in the medical area – Test method and requirements (phase 2, stage 1) (or, respectively: EN 13624:2003);
    - PN-EN 13727:2012 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, stage 1) (or, respectively: EN 13727:2012);
    - PN-EN 14348:2006 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants used in the medical area, including those used for disinfection of instruments – Test method and requirements (phase 2, stage 1) (or, respectively: EN 14348:2005);
    - PN-EN 14561:2008 – Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of bactericidal activity of chemical disinfectants intended for instruments used in the medical area – Test method and requirements (phase 2, stage 2) (or, respectively: EN 14561:2006);
    - PN-EN 14562:2008 – Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity against yeast–like fungi of chemical disinfectants intended for instruments used in the medical area – Test method and requirements (phase 2, stage 2) (or, respectively: EN 14562:2006);
    - PN-EN 14563:2012 – Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants for instruments used in the medical area— Test method and requirements (phase 2, stage 2) (or, respectively: EN 14563:2008);
2. Declaration of Conformity for compliance with the requirements of Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of medical devices (Journal of Laws, item 211) Declaration of Conformity for compliance with the requirements of Directive 93/42/EEC or Declaration of Conformity for compliance with the requirements of Regulation (EU) 2017/745
3. CE marking

Disinfectants, as biocidal products, shall comply with the requirements set out in the Law of 9 October 2015 on biocidal products and requirement of the Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Official Journal of the European Union L 167 of 27.06.2012, p. 1). They should have relevant marketing authorisations and be included in the List of Biocidal Products.

suits

Suits (protective clothes) shall comply with the following requirements:

1. compliance with the following standards:
    - PN-EN 14126:2005 – Protective clothing – Performance requirements and tests methods for protective clothing against infective agents (or, respectively: EN 14126:2003 EN 14126:2003/AC:2004)
2. Declaration of Conformity for compliance with the requirements of Regulation (EU) 2016/425
3. CE marking

surgical gowns / gowns for operating suites

Gowns shall comply with the following requirements:

1. compliance with the following standards:
    - EN 13795-1:2019 – Surgical clothing and drapes – Test method and requirements – Part 1: Surgical drapes and gowns (or, respectively: EN 13795-1);
    - EN 13795-2:2019 – Surgical clothing and drapes – Test method and requirements – Part 2: Clothing for operating suites (or, respectively: EN 13795-2);
    - PN-EN ISO 22610:2007 – Surgical drapes, gowns and clothing for operating theatres, used as medical devices for patients, medical staff and equipment – Test method to determine the resistance to wet bacterial penetration (it is the standard referred to above in letter (a))
    - PN-EN ISO 22612:2006 – Clothing for protection against infectious agents – Test method for resistance to dry microbial penetration (the standard referred to in letters (a) and (b))
2. Declaration of Conformity for compliance with the requirements of Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of medical devices (Journal of Laws, item 211) Declaration of Conformity for compliance with the requirements of Directive 93/42/EEC or Declaration of Conformity for compliance with the requirements of Regulation (EU) 2017/745
3. CE marking

FAST-TRACKING THE SUPPLY OF DISINFECTANTS IN POLAND DURING COVID-19

Procedural simplifications for the so-called fast-track registration of biocidal products and permission for using the Trusted Profile implemented by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products pursuant to the decisions issued on 13 march 2020 and then updated on 20 march 2020.

According Article 55(1) of the BPR and pursuant to National derogations, from the normal authorisation procedure may be granted for a period not exceeding 180 days.
An extension may be granted, for a period not exceeding 550 days. This is granted by the Commission. Conditions may be attached to these extensions. The Commission can only act where it receives a reasoned request from the national competent authority who originally granted the derogation.
This means that if you benefit from a derogation you may have to raise the need for an extension directly with competent national authorities.