



# Spotlight

## The requirements of EN ISO 21420

Explaining the detail contained within this new protective glove standard.



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EN ISO 21420:2020 – ‘Protective gloves – General requirements and test methods’ is the new general requirements standard for protective gloves. This standard has superseded EN 420:2003+A1:2009 and has been adopted by ISO to become a worldwide standard. The scope of this new standard includes protective gloves, arm protectors, gloves permanently incorporated in containment enclosures, mittens and pot holders. The requirements of this standard need to be satisfied for all protective gloves for all categories of PPE, and Notified Bodies will require test reports for category II and III protective gloves. Under the PPE Regulation, products must be ‘state-of-the-art’ – hence, protective gloves will need to be in accordance with the latest requirements standards. Therefore, once this new standard is harmonised, all new EU type-examination applications for protective gloves must be assessed against EN ISO 21420:2020.

Some of the key requirements listed under this standard are glove design and construction, chemical innocuousness, comfort and efficiency (sizing and dexterity) and information supplied by the manufacturer. This standard does not assess the protective properties of gloves and should therefore be used alongside any relevant specific requirement standards – such as those which evaluate mechanical, thermal or chemical protection.

# Glove design and construction

Requirements and guidance for glove design and construction are outlined in clause 4.1. This guidance describes that the protective gloves must not impair performance of the activity, while providing adequate protection from risk.

A new consideration under this standard is the donning and doffing of protective gloves. During these actions, layers of reusable multi-layered gloves must not become separated, and the design of the gloves must minimise the time needed for donning and doffing.

## Innocuousness

Chemical innocuousness is considered to ensure that protective gloves do not adversely affect the health or hygiene of the wearer. The materials present in the gloves must not, under foreseeable conditions of normal use, release substances generally known to be toxic, toxic to reproduction, carcinogenic, mutagenic, allergenic, corrosive, sensitising or irritating. This is outlined in clause 4.2 of the standard.

Requirements include:

**chromium VI** – applicable to all leathers; less than 3mg/kg

**nickel release** – applicable to metallic components in prolonged contact with skin; less than 0.5µg/cm<sup>2</sup>/week

**pH value** – applicable to all materials; requirement: pH value is to be greater than 3.5 and less than 9.5. Each material must be tested separately

**azo colourants** – applicable to all dyed leathers and textiles; requirement: less than 30mg/kg for each of the carcinogenic aromatic amines listed in the analysis methods

**dimethylformamide (DMFa)** – applicable to all materials containing polyurethane (PU); less than 1,000mg/kg (1 per cent w/w)

**polycyclic aromatic hydrocarbons (PAHs)** – applicable to rubbers and plastics in direct contact with the skin; less than 1mg/kg of each of the eight restricted PAHs.

In addition to those substances specifically listed in the standard, Notified Bodies may also require evidence of compliance with restricted substances legislation, such as REACH (Regulation (EC) No 1907/2006) Annex XVII. Pentachlorophenol (PCP) – a restricted fungicide – is listed in entry 22 of Annex XVII, and is applicable to leathers and natural textiles. The requirement is less than 1,000mg/kg (less than 5mg/kg in Germany). Also, entry 51 restricts the presence of four phthalate plasticisers in articles to a total of less than 0.1 per cent by mass of the plasticised material. The plasticisers are added to increase the polymer's softness and flexibility and this requirement is particularly relevant for vinyl gloves. The four plasticisers are i) bis(2-ethylhexyl) phthalate (DHEP), ii) dibutyl phthalate (DBP), iii) benyl butyl phthalate (BBP), and iv) diisobutyl phthalate (DIBP).

## Comfort and efficiency

Clause 5 of the standard outlines the requirements for sizing and dexterity of gloves. Dexterity is defined as 'the manipulative ability to perform a task with the hands'.

Sizing is defined based on the hand sizes that gloves are intended to fit. The sizes outlined under this standard cover the range of size 4 to size 13. The criteria assessed to determine sizing compliance include hand circumference and hand length (the distance from the wrist to the tip of the middle finger).

Minimum glove length can be defined and measured if required for a specific use (for example welder's gloves or firefighter's gloves). However, this is not specified under general requirements for gloves. In

addition to this, different sizing systems can be used if they are explained in the terms of EN ISO 21420:2020. This information would need to be outlined in the user information sheet provided with the protective gloves.

Glove dexterity is determined by multiple factors, including thickness of glove material and elasticity. When assessing glove dexterity, four gloves are tested. Dexterity is graded by the diameter of the smallest steel pin that can be picked up from a flat surface three times in 30 seconds. If no pin can be picked up, the level achieved is zero. If required, finger dexterity can be assessed for a specific use.

Clause 5.3 outlines optional requirements for breathability and comfort. Within this clause, requirements are given for claiming water vapour transmission and absorption. Water vapour transmission for leather gloves is assessed in accordance with ISO 14268:2012 to a requirement of 5mg/cm<sup>2</sup> per hour, and in accordance with ISO 11092:2014 to a requirement of 30m<sup>2</sup> Pa/W for textile gloves.

Water vapour absorption should be considered where the protection characteristics of the glove inhibit water vapour transmission. This means that, as an alternative, the gloves should be designed to reduce absorption of perspiration where possible. This is outlined in clause 5.3.2, which gives a requirement of 8mg/cm<sup>2</sup> per hour for leather gloves when tested in accordance with ISO 20344:2011.

## Electrostatic properties

The additional requirements outlined in clause 4.4.1 are relevant for all protective gloves intended to be worn in areas that present explosive or flammable risks. In this instance, if electrostatic properties are claimed, they must be tested in accordance with EN 16530:2014 and the pictogram shown in figure 1 can be used for marking. Where necessary, EN 1149 parts 1:2006 or 3:2004 should be used to determine further surface electrostatic properties of the gloves. This is relevant to determining further additional requirements of surface electrostatic properties or charge decay.

## Notable changes from EN 420:2003+A1:2009

The changes or additions from EN 420:2003+A1:2009 should be considered by Notified Bodies when assessing certification applications to update the technical files for gloves that have already been type-approved using EN 420:2003+A1:2009.

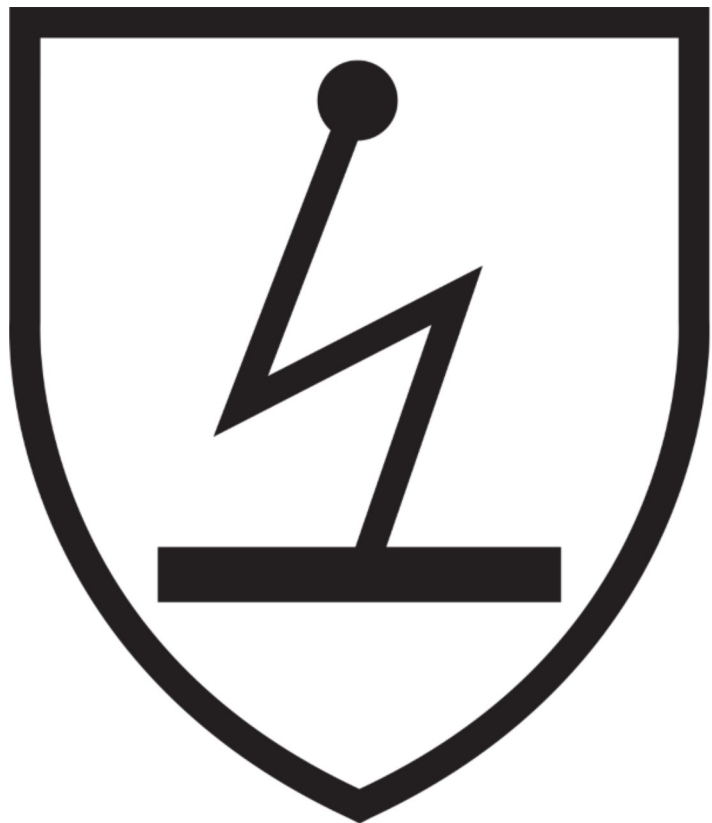


Figure 1: Marking pictogram for electrostatic properties of gloves to EN 16350

- re-usable multilayer gloves must be taken off without separation of the layers, as outlined in clause 4.1
- the resistance of glove materials to water penetration performance levels are no longer included. This testing was optional in EN 420 dependant on the intended use of the glove
- gloves that are intended to be worn in areas where flammable or explosive risks might be present need

to be tested for electrostatic properties in accordance with EN 16530. Previously (in EN 420), the test methods referenced were EN 1149 parts 1, 2 or 3, and the electrostatic pictogram could not be used

- it is important to be aware that a list of known allergens present within a protective glove is to be supplied if requested, and a list of such substances can be found in EN ISO 21420 Annex G.



*Nitrile gloves being used in a medical environment*

There have also been a few changes to the requirements for chemical innocuousness of gloves. Firstly, determining the presence of extractable proteins in natural rubber latex gloves is no longer listed as a mandatory assessment. However, a warning ('the glove contains natural rubber which may cause allergic reactions') must be included for gloves containing any natural rubber. In addition, there are new requirements to test for the presence of nickel release, azo colourants, DMFa and PAHs.

Due to the ever-growing initiative for sustainability, there are also additional environmental aspects to be considered (outlined in Annex F). EN ISO 21420 has also included references to both REACH and the Classification, Labelling and Packaging (CLP) regulation for hazardous substances to ensure that the chemical innocuousness assessments keep up-to-date with the latest chemical restrictions.

## How can we help?

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Please email [ppe@satra.com](mailto:ppe@satra.com) for further information about the testing and EU-type examination of protective gloves.

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