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Reading the runes: demystification of disposable glove legislation

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The use of disposable gloves in the general working environment is widespread. Indeed they are such a big part of our working lives that glove usage in the US has dramatically increased from less than 1 billion to over a 20 billion. We tend to use disposable gloves for either process protection from human-borne contamination or for personal protection and often for both reasons. However as safety in the occupational environment becomes an increasing concern, do we really understand what level of protection we are getting?

Key words: Disposable gloves, latex gloves, nitrile gloves, Medical Device Directive, Personal Protective Equipment

Introduction

For many individuals working in a cleanroom, the wearing of disposable gloves has become common practice. Indeed they are such a big part of our working lives that glove usage in the US has dramatically increased from less than 1 billion to over a 20 billion. We tend to use disposable gloves for either process protection from human-borne contamination or for personal protection and often for both reasons. However as safety in the occupational environment becomes an increasing concern, do we really understand what level of protection we are getting?

Those of us who have the time to decipher the pictograms displayed on the product may be surprised by the different legislation being used on gloves. Typically, disposable gloves are classified according to Council Directive 93/42/EEC for the Medical Device Directive (MDD) or Council Directive 89/686/EEC for Personal Protective Equipment (PPE). As the names may suggest, the primary concern for MDD is protecting the patient whilst PPE focuses on protecting the glove wearer. Therefore for gloves worn in the cleanroom where there is a requirement for personal protection, one would suppose that gloves registered according to the PPE directive would be used. Unfortunately, this is not always the case as those responsible for sourcing gloves may not know the difference between PPE and MDD.

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How to identify a glove registered according to the Medical Device Directive (MDD)

Underneath the CE mark, a reference to the standard EN455 "Medical gloves for single use" may sometimes features providing easy identification (**Figure 1**).

CE **EN455**

Figure 1. CE mark for MDD glove with EN455 standard.

Typically non-sterile gloves that are registered according to the MDD are labelled on the packaging as "Exam Gloves" or "Medical Examination Gloves", highlighting their role in patient care. It should be noted that these gloves are considered Class 1 medical devices* and as such undergo a self-certification process that is conducted directly by the manufacturer. Unlike sterile exam gloves or surgical gloves, there is no independent validation of the test data by an external organization.

(*The MDD defines four different classifications of medical device. These classifications are Class I, Class IIa, Class IIb and Class III, highlighting the ascending levels of risk to the patient. Non-sterile examination gloves are considered to be of the lowest level of risk and as such are Class I).

Some of the key features of the standards that might be used to demonstrate an MDD registration are as follows:

EN455-1 Pinholes based usually on a water leak test for a specified number of gloves. Compliance to MDD brings the benefit that gloves must meet an Acceptable Quality Level (AQL) of 1.5 using an inspection level of G1. An AQL of 1.5 brings a statistical probability that no more than 1.5% of the gloves will have pinhole defects. Whilst the average is 1.5%, the maximum percentage of gloves to fail on an inspected batch with AQL 1.5 can be as high as 3.17%. In a hospital environment, the test is significant in so far as it indicates the level of barrier protection being offered to the patient.

EN455-2 Physical measurements covering dimensions and most importantly tensile strength. The latter is measured in Newtons (N) and assesses the amount of force applied to a glove until it breaks. For each glove material, EN455-2 provides a minimum standard. For natural rubber latex exam gloves this is 9N, while for a natural rubber latex surgical glove it is 12N. Tensile strength is relevant, as it measures how materials of the same thickness respond to pressure. Also significant is that tensile strength is not a requirement of the PPE directive.

EN455-3 For natural rubber latex gloves, the natural rubber latex protein content must be tested. Manufacturers may not claim below 50mcg/g of water extractable protein.

EN10993-10 As part of EN455-3, a risk assessment needs to be conducted (as defined in EN1441 or EN ISO 14971) to determine the potential of the gloves to cause adverse reactions. Part of this process may entail testing the gloves for their biological safety (in accordance with ISO 10993) and particularly with reference to cytotoxicity, sensitisation and irritation.

How to identify a glove registered according to the Personal Protective Equipment (PPE) Directive

We have established that gloves for use in the cleanroom are typically associated with personal protection and therefore gloves covered by the PPE directive may be the most appropriate. However, what should we be looking for and how does the PPE directive help us in terms of giving us optimum protection? In order to assist personnel engaged in health and safety audits to identify the appropriate PPE to match the hazards and risks, PPE is categorized as Simple Design (often referred to as Category 1) or Complex Design (Category 3). Intermediate design (Category 2) gloves are those gloves that do not fall into either complex design or simple design categories.

How can Simple Design gloves help me in the cleanroom?

Simple Design is considered to be low risk and as such Simple Design gloves are defined as those gloves that protect the wearer from cleaning materials of weak action and easily reversible effects. Gloves giving protection against diluted detergent solutions are given as an example. Apart from bearing the CE mark, simple design gloves should mention clearly “For minimal risks only” in at least the official language of the country of destination. Significantly Simple Design is a self-certification process that imposes no obligation on the manufacturer to conduct tests according to certain standards. Whilst there is an expectation that the manufacturer will compile a technical file (of which the key elements might include manufacturing procedures, ISO compliance, quality control systems, packaging specifications, complaints procedures etc), there is no external validation. From this description it would appear that Simple Design gloves may have a limited role in the cleanroom, where protection from chemicals and micro-organisms may be sought.

What additional value do Complex Design gloves bring to my cleanroom?

Complex Design covers the highest level of risk, otherwise defined as irreversible and mortal risk. Disposable gloves in this category are typically those gloves that provide protection against chemical splashes and micro-organisms. For these gloves the following normative references may apply: EN374-1 (terminology and performance requirements), EN374-2 (resistance to penetration by chemicals and micro-organisms), EN374-3 (resistance to permeation by chemicals), EN388 (mechanical risks) and EN420 (general requirements for gloves).

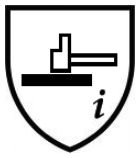
Crucially complex design brings the need for regular auditing by an external organization body, called a Notified Body. The presence of the Notified Body is clearly evident, as under the CE mark will appear four digits (e.g. 0120 = SGS, 0493=Centexbel, 0321=Satra, 0123=TÜV etc): **Figure 2**. The Notified Body validates the quality assurance system used by the manufacturer.

Figure 2. CE mark for Complex Design glove with four digits.

In addition, disposable gloves that have been registered as Complex Design will typically display two or three pictograms, depending on whether they have been tested according to the 1994 or 2003 versions of the norms relating to the PPE directives (**Table 1**).

Testing for compliance to Complex Design can take two forms: Article 11A “EC quality control system for the final product” entails testing of samples by the Notified Body and checks at least every year of the manufacturing

Table 1. Comparison of different pictograms used in 1994 and 2003 norms.

	1994	2003
EN374-3: 3 Tested for protection against chemical permeation		 EN374- AKL
Low chemical resistant or 'waterproof' gloves.		
EN388: Tested for protection against mechanical risks (abrasion, blade cut resistance, tear resistance & puncture resistance)		Unlikely to be displayed as few if any disposable gloves will achieve performance level rating of more than zero
EN374-2: Tested for protection against liquid penetration and micro-organisms		EN374-2  Level 2
Instructions for use	Usually incorporated in the pictogram as 'i'	

facility to ensure homogeneity with the product featured in the EC-type examination certificate. With Article 11B "System for ensuring EC quality of production by means of monitoring", testing may be conducted by the manufacturer but the quality control procedures of the manufacturer are periodically audited by the Notified Body. These details are important as it may help to explain why some manufacturers continue to use the 1994 version of the standards relating to the PPE directive and others the 2003 version. Whilst the Article 11A route obliges the Notified Body to use the latest norms, there does not appear to be any such obligation for manufacturers selecting the internal auditing option of Article 11B.

What is the significance of 1994 and 2003 PPE norms for my cleanroom?

The 1994 version of the norms did not differentiate between thin gauge disposable gloves designed for incidental exposure to chemical splashes and thicker gauge gloves intended for immersion. Indeed for all the relevant normative references (i.e. EN388, EN374-2 and EN374-3), testing was the crucial element for achieving registration. With regard to the mechanical risks pictogram (EN388: 1994), few if any disposable gloves would have the necessary properties to achieve anything more than a performance level rating of "0" for the four specific mechanical tests (resistance to abrasion, blade cut resistance, tear resistance and puncture resistance). Likewise for chemical permeation (EN374-3: 1994), selection of the four chemicals to be tested was left to the manufacturer, while the outcome mattered little so long as the testing had been done. In all cases the "i" on the pictogram referred the user to more detailed test data displayed on the glove dispenser box. Testing for protection against liquid penetration and micro-organisms (EN374-2: 1994) gave manufacturers a choice of levels of pinholes (Acceptable Quality Levels or "AQL" of 4, 1.5 and 0.65), without stating a minimum level.

In view of the possible confusion between the levels of protection being offered by thin gauge disposable gloves versus thick gauge gloves, the 2003 version of the standards relating to the PPE directive imposes more rigorous testing criteria:

EN388: 2003 (protection from mechanical risks) – this pictogram can only be displayed if the glove achieves a performance level rating of one in at least one of the four specific tests.

EN374-3: 2003 (determination of resistance to permeation by chemicals) – this glass beaker pictogram (**Figure 3**) can now only be displayed if a breakthrough time of at least thirty minutes (permeation performance level: 2) has been achieved in three of the twelve listed chemicals (**Table 2**). The code letters of the three tested chemicals must now feature below the pictogram. In each chemical class, it would appear that the most aggressive chemical has been selected giving the glove wearer a worse case scenario for chemicals in that particular classification. Consequently EN374-3: 2003 represents a significant improvement on the previous version, in terms of its value to those seeking protection from chemicals. However closer scrutiny of the twelve selected chemicals would suggest that with the exception of some thicker gauge surgical style gloves, no standard thin gauge disposable glove in whatever material would achieve the required level 2 in three out of the twelve listed chemicals.

EN374

Figure 3. Chemical pictogram for chemical protective glove.

To highlight the limitations of the chemical barrier properties of standard thin gauge disposable gloves and to emphasize that these gloves are designed only for

incidental exposure to chemical splashes, EN374: 2003 has given us a new pictogram (**Figure 4**). The question mark in the middle of the square-shaped glass beaker reminds those of us engaged in risk assessments that we are referring to "low chemical resistant" or "waterproof" gloves. Significantly there is no obligation for the manufacturer to undertake any testing on the twelve listed chemicals and the new pictogram only tells us that the gloves have fulfilled the penetration test (EN374-2: 2003). Whilst it is prudent to seek advice from the manufacturer on actual breakthough times with a particular chemical, we should not forget that this test data will often be based on deep immersion of the glove into the chemical and therefore may not offer a realistic representation of a work situation where the focus is on splash protection. Also it should be noted that any test data is likely to be done on an unused glove and does not reflect the actual workplace situation, where the used glove is subjected to many other stresses that are beyond the scope of a simple laboratory test.

Table 2. List of test chemicals.

Code letter	Chemical	CAS N°	Class
A	Methanol	67-56-1	Primary alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile Compound
D	Dichloromethane	75-09-2	Chorinated paraffin
E	Carbon disulphide	75-15-0	Sulphur containing organic compound
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	Tetrahydrofurane	109-99-9	Heterocyclic and ether compound
I	Ethyl acetate	141-78-6	Ester
J	n-Heptane	142-85-5	Saturated hydrocarbon
K	Sodium hydroxide 40%	1310-73-2	Inorganic base
L	Sulphuric acid 96%	7664-93-9	Inorganic mineral acid

Figure 4. Chemical pictogram for waterproof and low chemical protective gloves.

EN374-2: 2003 (determination of resistance to penetration by chemical and/or micro-organisms through porous material). An important test for some cleanroom personnel in the healthcare sectors, as it also gives us an indication of the barrier properties of the glove to liquid-borne biohazards. For most disposable gloves, the water leak test is used, where according to the inspection level based on ISO 2859 a specified number of gloves from every batch are filled with water to assess the levels of pinholes. Levels of pinholes are measured in terms of AQL or Acceptable Quality Level, with an AQL of 0.65 having a lower level of acceptable pinholes than 4.0. To display the pictogram (**Figure 5**) and as part of the process for satisfying a Complex Design registration, gloves must have a minimum AQL of 1.5. EN374-2: 2003 describes the levels, which are often displayed underneath the pictogram (**Table 3**).

Figure 5. Pictogram for micro-biological hazards.

Table 3. Inspection levels and AQL outlined in EN374-2:2003.

Performance level	Acceptable quality level (AQL) unit	Inspection levels
Level 3	<0.65	G1
Level 2	<1.5	G1
Level 1	<4.0	S4

More about Complex Design disposable gloves and their use in the cleanroom

We have already seen how the 2003 version of the standards relating to the PPE directive represents a significant evolution in terms of providing greater clarity to glove wearers in the cleanroom. However interpretation of these norms does continue to provide divergence in compliance. Even different Notified Bodies seem to be able to interpret the norms in different ways, leading to potentially conflicting results. Here are two examples:

Minimum length of glove

Whilst both the 1994 and 2003 versions of EN420 "General requirements for protective gloves" give minimum lengths for gloves, various exclusion clauses allow manufacturers to supply shorter lengths so long as justification is provided. However EN374-1: 2003 makes it clear that for protective gloves against chemicals and micro-organisms, the minimum length of the liquid proof section of the glove shall not be less than that specified in EN420. This tightening up of the standard is presumably to provide extra protection to the wrist. Whilst this change may be entirely laudable, many standard Complex Design disposable gloves are 24cm or 10". However, according to EN420 the minimum length for sizes 9 (L) and 10 (XL) should be respectively 25 cm and 26 cm. This aberration in the interpretation of the standards even includes gloves claiming registration based on the 2003 standards, where the testing would have been done by a Notified Body as part of the verification process against Article 11A "EC quality control system for the final product".

Protection from viral penetration

With the healthcare sector expressing increasing concern about personal protection from biohazards, clarification on the barrier protection offered by disposable gloves may be of interest. As we now know, the micro-organism or liquid penetration pictogram (**Figure 5**) (as defined in EN374-2: 2003) is the standard to which we must refer. However, this standard is typically based on the water leak test and may not provide complete assurance as to the barrier properties of the glove when challenged by a microbial agent. In this respect clause 3.2 of EN374-1: 2003 states that whilst the test methodology of EN374-2 (2003) is sufficient for demonstrating that the gloves provide an effective barrier to bacteria and fungi, this does not extend to protection against viruses. Indeed some Notified Bodies are now insisting that the cautionary statement of "Does not protect against viruses" is included with the general information. If this is a concern to health & safety personnel, gloves that have undergone the viral penetration test (ASTM F1671) could be the solution.

Conclusion

We have seen that checking the details on the packaging of our disposable gloves may help to ensure that we are using the appropriate gloves for use in the cleanroom. Whilst disposable gloves that are registered according to the Medical Device Directive may have some useful features, these gloves are designed to protect the patient and are not for personal protection. In a cleanroom environment where personal protection from chemical splashes and biohazards may be sought, only those disposable gloves that comply with the Personal Protective Equipment Directive: 89/686/EEC should be used. In this context, the limitations of Simple Design gloves and the emphasis on protection from chemicals and micro-organisms would suggest that those gloves that are registered as Complex Design are the most appropriate.

References

EN374-1:2003 (supersedes EN374-1:1994) Protective gloves against chemicals and micro-organisms – Part 1: Terminology and performance requirements

EN374-2:2003 (supersedes EN374-2:1994) Protective gloves against chemicals and micro-organisms – Part 2: Determination of resistance to penetration

EN374-3:2003 (supersedes EN374-3:1994) Protective gloves against chemicals and micro-organisms – Part 3: Determination of resistance to permeation by chemicals

EN388:2003 (supersedes EN388:1994) Protective gloves against mechanical risks

EN420:2003 (supersedes EN420:1994) Protective gloves – General requirements and test methods

EN455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes

EN455-2:2000 Medical gloves for single use – Part 2: Requirements and testing for physical properties

EN455-3:2000 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

ASTM F1671-07 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Bllod-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

EN1441:1998 Medical Devices – Risk Analysis

EN ISO 14971: 2001 Medical Devices – Application of risk management to medical devices

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