Deciphering the **code**

Glove selection requires a basic understanding of complex regulation and standards involving codes and pictograms. **Cisco Robles**, general manager of Shield Scientific, attempts to demystify the legislation

For many individuals working in a cleanroom, the wearing of disposable gloves has become common practice. Indeed glove usage in the US has increased from fewer than 1 billion to more than 20 bn.

Disposable gloves are usually used for either process protection from human-borne contamination or personal protection – and often for both. 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 Directive 93/42/EEC for the Medical Device Directive (MDD) or Directive 89/686/EEC for Personal Protective Equipment (PPE).

As the names suggest, the primary concern for MDD is protecting the patient, while 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 sourcing gloves may not know the difference between PPE and MDD.

Working to the MDD

Underneath the CE mark, a reference to the standard EN455 "Medical gloves for single use" may sometimes feature, providing easy identification.

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EN455

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.

Key features of the standards that may be used to demonstrate a MDD registration are:

- **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.

While 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, as it indicates the level of barrier protection offered to the patient.

- **EN455-2:** Physicals 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.

	1994	2003
EN374-3 Tested for protection against chemical permeation		a  EN374-3 AKL
Low chemical resistant or waterproof gloves		b 
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		c  EN374-2 Level 2
Instructions for use	Usually incorporated in the pictogram as "*i*"	

Table 1: Pictograms used in the 1994 or 2003 versions of the norms for the PPE directives

- **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.

Working to PPE

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 look for and how does the PPE directive help us in terms of giving us optimum protection? To assist in identifying the appropriate PPE to match the hazards and risks, PPE is categorised as Simple Design (Category 1) or Complex Design (Category 3). Intermediate design (Category 2) gloves are those that do not fall into either Complex Design or Simple Design categories.

- **Simple Design gloves:** These are considered to be low risk and 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 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.

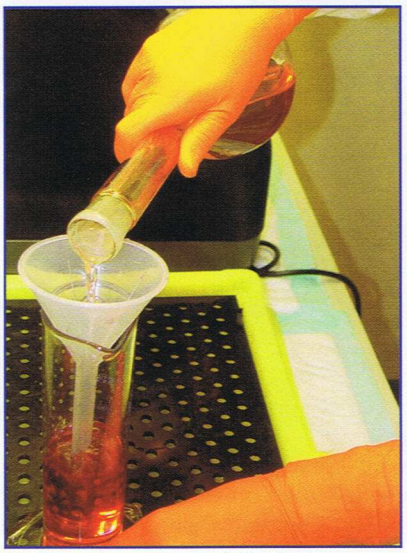
Significantly, Simple Design is a self-certification process that imposes no obligation on the manufacturer to conduct tests according to certain standards. While there is an expectation that the manufacturer will compile a technical file (the key elements of which might include manufacturing procedures, ISO compliance, QC 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.

- **Complex Design:** This covers the highest level of risk, otherwise defined as irreversible and mortal risk. Disposable gloves in this category typically 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 organisation body, or "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). The Notified Body validates the QA system used by the manufacturer.

CE 0123

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 to the 1994 or 2003 versions of the norms relating to the PPE directives (see table 1).



Complex Design gloves offer protection from chemicals and micro-organisms

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 of the manufacturing facility at least every year 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 manu-facturer but the QC procedures of the manufacturer are periodically audited by the Notified Body. These details 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. While 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.

The 1994 version of the PPE 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 (AQLs 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 be displayed only if the glove achieves a performance level of one in at least one of four specific tests.
- **EN374-3: 2003** (determination of resistance to permeation by chemicals) – the glass beaker pictogram (table 1, a) can now be displayed only if a breakthrough time of at least 30 mins (permeation performance level: 2) has been achieved in three of the 12 listed chemicals (see 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 worst 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 12 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 12 listed chemicals.

To highlight the limitations of the chemical barrier properties of standard thin gauge disposable gloves and to emphasise that these gloves are designed only for incidental exposure to chemical splashes, ▶

Table 2: Determination of resistance to permeation by chemicals

Code	Chemical	CAS No	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	Chlorinated 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	Tetrahydrofuranel	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

◀ EN374: 2003 has given us a new pictogram The question mark in the middle of the square-shaped glass beaker (table 1, b). 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 12 listed chemicals and the new pictogram tells us only that the gloves have fulfilled the penetration test (EN374-2: 2003).

While it is prudent to seek advice from the manufacturer on actual breakthough times

Table 3:

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

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 on an unused glove and does not reflect the workplace situation, where the used glove is subjected to many other stresses.

EN374-2: 2003 (determination of resistance to penetration by chemical and/or micro-organisms through porous material). This is an important test for 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, with an AQL of 0.65 having a lower level of acceptable pinholes than 4.0. To display the pictogram c (table 1) 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 often displayed underneath the pictogram (see table 3).

Open to interpretation

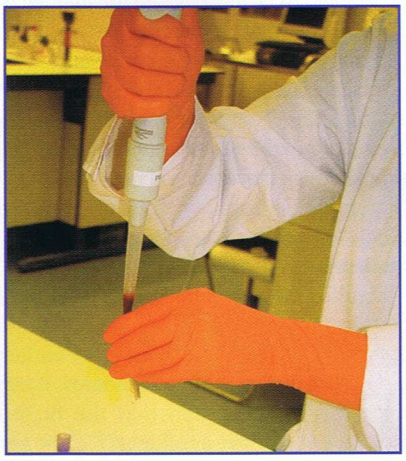
We have already seen how the 2003 version of the standards relating to the PPE directive represents a significant evolution in terms of providing greater clarity to glove wearers in the cleanroom. However interpretation of these norms does lead to divergence in compliance. Even different Notified Bodies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

Minimum length of glove: While 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 as 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.

While this change may be laudable, many standard Complex Design disposable gloves are 24cm (10 in). However, according to EN420 the minimum length for sizes 9 (L) and 10 (XL) should be 25cm and 26cm respectively. This aberration in the interpretation of the standards even includes gloves claiming registration based on the 2003 standards, where the testing would have been 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 health-care sector expressing growing 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 (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 while 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 personnel, gloves that have



undergone the viral penetration test (ASTM F1671) could be the solution.

Checking the details on the packaging may help to ensure the appropriate disposable gloves are used in the cleanroom. While disposable gloves that are registered according to the MDD may have some useful features, they are designed to protect the patient rather than for personal protection. In a cleanroom, where personal protection from chemical splashes and biohazards may be sought, only disposable gloves that comply with the PPE 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 Complex Design gloves are the most appropriate. ■

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