Key regulations: Disinfection by the rules

When examining the regulations and directives governing the manufacture and sale of disinfectants and cleaners, **Clare Clark - BSc (Hons) Microbiology, ACIST, MRB**, technical support manager, schülke UK, explains why it is necessary to consider what constitutes a medical device (MD), and why this is significant.

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Regulations and directives surrounding the production and sale of disinfectants into the healthcare sector are complex. These regulations are of significance to NHS Trusts and some understanding is required to ensure that chosen cleaning and disinfection products meet legal requirements for use in the hospital environment. Also, as various EU directives come into force, a number of products which have not undergone the necessary processes and approvals will cease to be available.

This has already been experienced in the Republic of Ireland where a leading brand of alcohol based wipes has been discontinued as a direct result of not being supported through the essential directives. Whatever the outcome of Brexit, it is highly likely that the UK will continue to work with EU directives and regulations when it comes to classifying disinfectants and cleaners.

This article gives an outline of the key influencing regulations, what they mean in practice and an indication of the timescale over which they are being implemented.

The Medical Devices Regulation (MDR)

On 5 April 2017, two new regulations for medical devices were adopted, replacing the existing three directives. These new regulations will apply following a transitional period of three years for medical devices and five years for *in vitro* diagnostic medical devices.

Although the core legal framework consists of two regulations, the one which is applicable to disinfectants and cleaners used in the hospital environment is Regulation (EU) 2017/745 regarding medical devices. This part of the regulation covers products and equipment which will come into direct contact with the patient. A product such as a flexible endoscope is classified as a medical device and, according to the regulation, any product which is used to clean or disinfect a medical device must carry a CE mark.

The MDR provides guidance on defining a medical device (MD) and is based on the stated intended purpose of the product. According to this EU Regulation, a medical device is defined as: "any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used alone or in combination, for human beings for one or more of the specific purpose(s)' which includes 'products specifically intended for the cleaning, disinfection and sterilisation of medical devices."

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In general, for a disinfectant to be classified as a medical device, it must be specifically indicated for the disinfection of medical devices. For example, when reprocessing a flexible endoscope, which is categorised as a medical device (as it is used specifically for diagnostic and / or therapeutic purposes) a disinfectant with an MD certification must be used during the process.

The Medical Devices Regulation relates to the safety and performance of a product. For a manufacturer to legally place a device on the European market, the essential requirements of the directive must be met and a CE mark applied. These requirements ensure that a product is safe for its intended use and is fit for purpose. It must also carry appropriate labelling and relevant testing must have been carried out to a specified standard.

A CE mark is similar to the previously used UK Kite mark, but the CE marking is in line with EU regulations and directives. The letters "CE" are the abbreviation of the French phrase "Conformité Européene" which literally means "European Conformity". The term initially used was "EC Mark" and it was officially replaced by "CE Marking" in the Directive 93/68/EEC in 1993. "CE Marking" is now used in all EU official documents. CE marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. ▶

In essence it is the product's 'passport' within the EU and appears as a logo on medical devices to show they conform to the requirements in the directives. It indicates that the product may be legally placed on the market in their country. The logo shows that the device is fit for its intended purpose stated and meets legislation relating to safety.

CE marking on a product permits the withdrawal of non-conforming products by EEA (European Economic Area) customs and enforcement/vigilance authorities.

If a product is just intended to be used for cleaning it will only carry a CE mark and nothing else. For example, thermosept X-tra designed for the automated cleaning of medical devices and accessories has a CE mark on the label meaning that it is compatible with and authorised for use on surgical instruments, rigid endoscopes and other instruments commonly used in the central sterile supply department.

However, if a medical device is intended for use as a disinfectant the CE symbol is followed by a series of four numbers. Thermosept PAA for the automated disinfection of flexible endoscopes in AERs, is a class 2b medical device and the label carries the CE mark followed by the four digits - 0297.

Any cleaner or disinfectant which does not carry a CE mark should not be used in a healthcare setting such as a hospital.

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There is a set of agreed standards which must be followed to bring an MD for cleaning and disinfection to the market. ISO 13485 is an international standard that defines quality management system (QMS) requirements for manufacturers of medical devices. The primary objective of the standard is to facilitate harmonised QMS requirements for regulatory purposes within the medical device sector. It is applicable to all manufacturers of medical devices who have a duty to ensure that devices consistently meet customer requirements and meet all applicable regulatory requirements.

In addition, a company manufacturing a medical device must have established risk management processes that comply with ISO 14971:2007. This standard 'specifies a process for a manufacturer to identify the hazards associated with medical devices… ..to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.' The requirements of ISO 14971 are applicable to all stages of the life-cycle of a medical device. The MDR, ISO 13485 and ISO 14971 are the key building blocks underpinning product quality. All need to be in place to ensure the highest quality disinfectant or cleaner.

Biocidal Products Regulation

Products developed for disinfection may also come within the remit of the biocides regulations as well as the medical device regulations, depending on their intended purpose, composition and the claims made for the products concerned.

There are considerable differences between a medical device and a biocide. The MHRA states that biocides are 'intended as general purpose disinfectants for rooms, hard surfaces etc' and 'are not considered to be medical devices'. [MHRA, 2016] A biocide is approved based on its active substance, so it is only the active ingredient which is approved, not the final complete product, whereas an MD refers to the complete product.

The EU Biocides Regulation 528/2012 covers a diverse range of products which control harmful or unwanted organisms through chemical or biological means. These include disinfectants. The difference between MDR and BPR is that BPR applies to the disinfection of non-critical areas which do not come into contact with patients like floors and work tops. Whereas MDR covers products which are used to clean or disinfectant anything which comes into direct contact with a patient.

For critical healthcare areas a CE mark is required and for non-critical areas where disinfection is claimed, BPR registration is needed. In practice this means that a disinfectant used in the healthcare environment may need a dual registration and need to be registered according to both the BPR and MDR.

For example, the mikrozid range of surface cleaners has a dual registration as they have a biocidal formulation for the disinfection and cleaning of hard surfaces as

well as the disinfection of medical devices.

The process of authorising active substances for registration is currently underway. It is likely to take a number of years with 2024 being the estimated completion date. The first stage is the authorisation of active substances which need to be registered with a competent authority and 22 different product types are listed under BPR. Any substance not falling into one of these 22 categories or not being registered cannot be sold within the EU. A new active substance will need to be evaluated to ensure that it poses no unacceptable risks before products containing it can be authorised and made available on the market.

Once the active substance has been approved by the Biocidal Products Committee, there is a two year period in which to register the finished biocidal product. Some active substances have already been approved such as alcohol and are therefore currently going through the product approval stage. Once a product has gone through this process, an approval number is supplied which will be added to the label of the product. This means that some disinfectants may eventually carry both a CE and a BPR number.

As more active ingredients are approved, disinfectants in the UK will start to include a BPR number on their labels, until this time, Trusts can ask manufacturers if the product has or is in the process of applying for BPR registration. The process has already taken place in the Republic of Ireland where disinfectants now carry a BPR registration number on the label. Products not undertaking this process may not be available to purchase in the not too distant future.

If a manufacturer does not wish to undertake the lengthy and costly BPR registration process, they are obliged to remove the product from the market, as has already been seen with a particular brand of alcohol wipes. More disinfectants are likely to be withdrawn from sale as manufacturers fail to conform to BPR or decide to withdraw from sale within the EU.

The UK's likely withdrawal from the EU is not likely to change the way that MDR and BPR affect the classification and regulation of cleaners and disinfectants in healthcare settings in the UK. Manufacturers are intrinsically linked to Europe and this is unlikely to alter. In the meantime, Trusts should consider that not all cleaners and disinfectants will continue to be available, and not all will necessarily comply with the standards set out by the MDR and BPR. To protect both patients and staff, it is essential to check that all disinfectants and cleaners are compliant with the necessary regulations. CSJ

Reference

1 Medicines & Healthcare products Regulatory Agency (MHRA). (2016) Guidance on legislation Borderlines with medical devices

To learn more about 'Regulations, Norms and Guidelines' type the link below for 45 minutes' verifiable CPD based on a presentation to the Institute of Decontamination Sciences (IDSc) annual conference 2018, by Mr Wolfgang Merkens (Schulke & Mayr GmbH). The course has been designed in conjunction with the IDSc and includes the role of disinfectants in the decontamination process together with a review of criteria commonly used for the selection of disinfectants.
www.schuelke-learning.com/course/disinfection-selection-for-reprocessing-flexible-endoscopes