The case of the disappearing disinfectants

Clare Clark presents a guide to regulations and what they mean in practice.

This has already been experienced in the Republic of Ireland where a leading brand of alcohol based wipes have been discontinued by the manufacturer as a direct result of deciding not to implement essential regulations.

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

The Medical Device Directive and CE marks

The Medical Device Directive 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 specified standards.

Although the core legal framework consists of three directives, the one which is applicable to disinfectants and cleaners used in the dental practice is Directive 93/42/EEC regarding medical devices. This part of the directive covers products and equipment which will come into direct contact with the patient. A product like a spittoon, for example, is classified as a medical device and, according to the directive, any product which is used to clean/disinfect a medical device must carry a CE mark.

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.

Regulations and directives surrounding the production and sale of disinfectants into the healthcare sector are complex. It is therefore easy to dismiss these regulations as of little significance to a busy dental practice. However, some understanding is required to ensure that the chosen cleaning and disinfection products meet legal requirements for use in the dental environment. Also, as various EU directives come into force, a number of products which haven’t undergone the necessary processes and approvals will cease to be available.

Clare Clark is technical support manager at schülke UK.
governmental officials that the product may be legally placed on the market in their country.

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

A CE mark is similar to the previously used UK Kite mark, but the CE marking is in line with EU regulations and directives. If a product is only intended to be used for cleaning it will only carry a CE mark and nothing else. If it is intended for use as a disinfectant, the CE symbol is followed by a series of four numbers, which relate to the authorising body. For example, gigasept instru AF for disinfecting and pre-cleaning of instruments has CE 0297 on the label, meaning that it is compatible with, and authorised for, use on dental instruments.

Any cleaner or disinfectant which does not carry a CE mark should not be used in a healthcare setting, such as a dental practice, when reprocessing medical devices.

**Biocidal products regulation**
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 MDD and BPR is that BPR applies to the disinfection of non-critical areas which do not come into contact with patients, like floors and worktops; whereas, MDD covers products which are used to clean or disinfect 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 healthcare may need a dual registration and need to be registered according to both the BPR and MDD.

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. A disinfectant which is used on both medical devices and as a ‘killing cleaner’ on floors and surfaces must be dual registered.

The process of authorising active substances for registration is currently underway. It’s likely to take several 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 under one or more different product types 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 ethanol. Therefore, finished products based on this active substance are currently going through the product approval stage. Once a product has passed through this process, an approval number is supplied which will be added to the label of the product. This means that some disinfectants will eventually carry both a CE and a BPR number, which will be essential for supply into dental practices. As more active ingredients are approved, disinfectants in the UK will start to include a BPR number on their labels; until this time, practices can ask manufacturers if the product 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 withdrawal from the EU is not likely to change the way that MDD and BPR affect the selection of cleaners and disinfectants in healthcare settings in the UK. Manufacturers are intrinsically linked to Europe and this is unlikely to change after 2019. In the meantime, dental practices should be aware that not all cleaners and disinfectants will continue to be available and not all will necessarily comply with the standards set out by the MDD and BPR. To protect both patients and staff, it’s worth checking that your disinfectants are compliant.

---

**Could you be the ‘schülke Infection Prevention & Control Practice of 2017’?**

This is the final chance to register for the 2017 schülke Infection Prevention & Control Practice of the Year awards. schülke, specialist in infection prevention and control, is working in partnership with *The Dentist* to recognise the commitment of dental practices to infection prevention and control. The award is open to all dental practices across the UK and the winning team will receive their trophy at Dental Showcase at NEC, Birmingham, in October.

Registration could not be simpler, email your contact details to ipcaward.sm@schuelke.com. Every practice who registers will receive a short questionnaire which must be completed and returned by June 30. Shortlisted practices will be visited and interviewed by a member of *The Dentist* editorial team.

This year, the winning team will receive an autoclave worth £5,000 from NSK, as well as a trip to BDIA in Birmingham on October 20, to be presented with their winner’s trophy and certificate.