

Sterile or non-sterile – the choice is yours.....

Class 1 medical devices represent the majority of single use devices used in the UK today. Devices such as wooden tongue depressors, plastic forceps and scissors are used in their thousands every day for simple procedures and examinations. But what control is exercised over the manufacturers of such simple devices? This can depend largely on whether the device is sold as a sterile or non-sterile device.

The wording on the packaging of medical devices sold in the EU can be a little confusing, especially references to “clean” and “sterile” and the differences between them. What is the difference between “sterile” and “clinically clean” and what difference does the use of a sterile device make to the patient? For example, a Class 1 medical device such as a single-use vaginal speculum or proctoscope could be bought as sterile or non-sterile depending upon the choice of the clinician. However, the user should also be aware that there are different regulatory requirements for companies who manufacture sterile Class 1 devices versus non-sterile Class 1 devices.

The Regulatory Pathway

All medical devices sold in the EU must meet the requirements of the Medical Devices Directive, 93/42/EEC (MDD). However, the way in which these requirements are enforced depends largely upon the classification of the device. The more complex the device, the higher the class. Consequently, the higher the class, the more complex the regulatory pathway and the more difficult the route to market for the device manufacturer.

All manufacturers must have a quality system in place and must meet certain requirements relating to the way in which the device is manufactured. The degree of external intervention by a Notified Body (a certification company appointed by the Competent Authority (CA) to ensure that regulatory requirements are met) depends upon the classification of the device. In the UK, the Competent Authority is the Medicines and Healthcare products Regulatory Agency (MHRA).

This discussion centres around Class 1 medical devices, which are the simplest devices with the lowest overall risk to the user and the patient. Class 1 devices fall into four main categories:

- (1) Devices which are non-sterile and have no measuring function.
- (2) Non-sterile devices with a measuring function
- (3) Sterile devices with no measuring function
- (4) Sterile devices with a measuring function

Of these, category (1) require no intervention by a Notified Body. Categories (2), (3) and (4) require Notified Body certification for the sterility and/or measuring aspects of the device.

Non-sterile Class 1 Medical Devices

Class 1 devices are the lowest class of device and by definition the simplest, and these are subject to self-regulation. This means that the manufacturer can *self certify* the device in accordance with the requirements of 93/42/EEC and does not need a certificate issued by a Notified Body. The company must register with the Competent Authority as a manufacturer of Class 1 devices and the CA may choose to audit the company but in reality this rarely happens. This means that the company often has **no independent check of its quality system from one year to the next**. That's not to say, of course, that these manufacturers produce products of inferior quality, just that they need no third party intervention to allow them to place devices on the EU market. This is therefore seen as the simplest regulatory pathway and consequently the simplest, and often quickest, route to market. The manufacturer must apply a CE mark to the device to demonstrate compliance with the MDD but this will not have an associated Notified Body number.

“Clinically clean” is a term often used by suppliers of non-sterile devices to infer that whilst the device is non-sterile, it still has an adequate level of cleanliness to be fit for use in a given situation. **There is no legal definition of “clinically clean”**, but the Medical Devices Directive does tell us that *“devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties”*. It also states that *“packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated.”* The main issue here is that whilst the level of cleanliness may be stipulated in an internal company document, the manufacturer is not obliged to share this information with the user of the device. In other words, **the user of a non-sterile single use, Class 1 medical device has no way of knowing how clean the device is before it is used**. Any reference therefore on the packaging of a medical device to **“clean” or “clinically clean” has no real meaning and the level of cleanliness is not defined**.

What might be contaminating a non-sterile device? This depends upon a number of factors including the environment in which the device is manufactured and the materials and equipment from which the device is made. But the greatest influence on the level of contamination is the amount of handling the device is subjected to, for example, during assembly, inspection and packaging. Clearly, the more automated the manufacturing process, the less chance there is of contamination. Also, the more control exerted by the manufacturer on the health and hygiene of the production operators, the lower the risk of contamination. Products manufactured in a cleanroom with appropriately dressed manufacturing staff will have the lowest bioburden, or number of viable microorganisms on the device. **Typical microorganisms found on non-sterile medical devices are Bacillus spp., Micrococcus spp. Staphylococcus spp. and environmental yeasts and fungi**. Numbers can range from one or two organisms per device, to hundreds of organisms per device, again dependent upon the manufacturing environment, materials, equipment and handling. In a medium volume manufacturing facility such as one producing moulded vaginal specula, a single production operator could handle around 20,000 devices per month, that's 5000 per week, 1000 per day and potentially 250 – 300 between hand washes! The risk of transfer of organisms from a production operator to a device and on to a patient may be low on a case by case basis but when you consider that there are **10 million vaginal examinations performed annually in the UK**, and that around 15% of all single-use specula sold in the UK are non-sterile, the numbers start to add up.

But what are the implications for the user of a non-sterile class 1 medical device? Obviously this depends greatly upon the intended use of the device. A non-sterile cotton wool ball may be perfectly adequate for wiping the brow of an over heated patient but not for cleaning the eyes of a premature baby in SCBU. Similarly, non-sterile polythene tubing may be fine for carrying fluids away from the body but would not be suitable for transporting an intravenous infusion *towards* the body.

A vaginal speculum comes into contact with a (usually) intact mucous membrane. The device is classified as an “intermediate risk device” by Eucomed, and their guidance states that reusable specula should be decontaminated and sterilised using the same methods as for high risk devices, i.e. moist heat, dry heat, ethylene oxide, low temperature steam or sterilising agents such as formaldehyde. **Under what circumstances could you therefore imagine using a non-sterile speculum?**

What are the advantages, then of using a sterile, single-use Class 1 medical device?

Sterile Class 1 Medical Devices

There is a clear definition of “sterile” given to us in the harmonised European standard EN 556:1994. To be labelled as sterile, a medical device needs to have a sterility assurance level of 10^{-6} . This means that the manufacturer must be able to guarantee that the probability of the device being non-sterile is 1 in a million. To achieve this, the medical device manufacturer needs to have a well defined and controlled manufacturing process but more importantly, some elements of the system, particularly those relating to cleanliness and sterility, must be reviewed, audited and certified by a Notified Body. A sterile medical device sold within the EU must also be clearly labelled with two distinctive symbols.

The first is

STERILE	X
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 where X represents the method of sterilisation; R for ionising radiation such as gamma or electron beam, EO for ethylene oxide etc.

The second symbol is the CE mark. All medical devices sold within the EU must bear a CE mark and for non-sterile class 1 devices the mark will appear alone. Sterile class 1 devices will be labelled with the CE mark which will have an accompanying four digit number. This number is unique to the Notified Body who has assessed the capability of the manufacturer to manufacture sterile devices.

The MDD requires that *“devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.”* Thus, the Notified Body assessment must consider the stability of the product and the ability of the packaging to maintain sterility of the product until the package is breached.

The MDD goes on to say that *“devices delivered in a sterile state must have been manufactured and sterilised by and appropriate, validated method.”* And that *“devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.”*

The Notified Body's assessment therefore includes a review of the manufacturing environment for the product, the controls applied to the manufacturing process, the health and hygiene policies of the company and the validation of the sterilisation process used for the products. The method of validation will depend upon the sterilisation method, but must comply with the relevant harmonised standard for that method.

Notified Bodies visit certified manufacturers at least once per year which gives a high degree of assurance that controls are maintained within the manufacturing facility.

Failure of a manufacturer to meet the requirements of the MDD can result in certification being withdrawn and the company prevented from placing devices on the market.

Risks of Infection

All clinical examinations carry a risk of infection. Even procedures carried out in a sterile field using a set of sterile instruments can result in transfer of infective agents, from the clinician, the surroundings or transferred from another area on the patient's body. However, this **risk is greatly increased when non-sterile instrumentation is used.** As discussed earlier, microorganisms can be transferred from the manufacturing environment and personnel onto the device where they may be sealed in a package and exist in bacteriostasis or equivalent until the packaging is opened and the device is used on a patient. The organism may then be transferred into an ideal breeding environment, i.e. the human body, and cause infection.

The Department of Health recognises that Healthcare associated Infections (HCAIs) are caused by a wide variety of microorganisms. In most developed countries, around 6 – 10% of all hospital patients acquire an infection. A common infectious agent is *Staphylococcus aureus*, a common skin organism. One strain is resistant to the antibiotic methicillin - hence the acronym MRSA – methicillin resistant *Staphylococcus aureus*. In the year to March 2004 there were 19311 hospital acquired *Staphylococcus aureus* infections of which 7647 were MRSA.

The Government's View

The UK Department of Health clearly recognises the cost of healthcare acquired infections, both to the health of the British public and to the Department's financial budget. In July 2004, a policy document entitled "Towards cleaner hospitals and lower rates of infections" was published and is described as "an action plan for cleaner hospitals and lower rates of infection". This followed on from "Winning ways: working to reduce healthcare associated infections in England" which was published in December 2003. Both of these policy documents target HCAIs and MRSA in particular and recognise the importance of good hygiene in hospitals. The latter specifically introduces the *cleanyourhands* campaign which is to be launched by the Government this summer.

With so much emphasis on hospital hygiene and in particular the occurrence of HCAIs, it would seem to be in both the patient's and the clinician's best interests to further reduce the possibility of infection by using sterile devices whenever possible. **There may be a short term cost advantage to using the non-sterile option – perhaps a few pence per single-use device- but the long term cost to the health service could far outweigh this saving.**

Author – Annette E Callaghan, BSc(Hons), CBiol, MI Biol. Quality Management Consultant