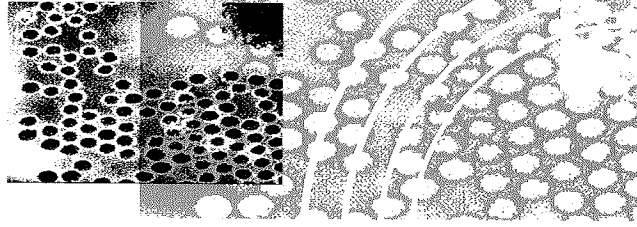


NEWS UPDATE



What's New in Standardisation Hollow Devices

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Standard EN 285 which was recently adopted is to be amended, while prEN 285-A1 was accepted at the first enquiry and will probably be put to a final vote already in the course of this year.

This amendment will focus on new requirements for steam penetration into hollow devices. Testing with a rubber load with biological indicators, featured hitherto as an option in EN 285, is to be omitted. Instead, testing with the hollow process challenge device (PCD) as per EN 867-5 will become a binding part of the standard. This standardized hollow test device featured in EN 867-5 is a 1.5 m long PTFE tube with 2 mm internal diameter and 0.5 mm wall thickness as well as with a capsule that acts as a closure for the tube at one end. In general, a chemical indicator system is inserted into the capsule. This chemical indicator makes more stringent demands on the process than does the rubber load.

25 years ago, EN 285 was drafted on the basis of the national standards valid at that time. A process that was able to ensure reliable sterilisation of textiles was deemed previously as qualifying without any reservations for sterilisation of instruments. This belief has been shown to be incorrect. Today, we know that steam sterilisation of instruments is associated with specific problems.

Accordingly, it cannot be assumed that a steriliser that has successfully passed the Bowie & Dick test will be able to sterilise hollow devices. Nor, conversely, can it be assumed that the Bowie & Dick test will be successful if the test performed with

the standard PCD as per EN 867-5 has been passed. Therefore EN 285 stipulates conductance of both tests in future.

EN 13060 regulating small steam sterilisers defines an object as a hollow device if its depth is greater than its diameter; hence, in the context of EN 13060 dishes and bowls do not qualify as hollow devices. This is misleading because in the gravitation process such dishes are sterilised only if their opening points downwards. Massive instruments placed in such dishes cannot be sterilised in simple small sterilisers. EN 13060 also defines a type B hollow device with a diameter of at least 5 mm and a depth that does not exceed fivefold the diameter. There are few real-life instruments that meet this definition. So all sterilisers used for devices with gaps or lumens should be tested with the hollow PCD, which is now also is to be used for testing in large sterilisers.

EN 13060 presupposes that hollow devices whose relation of length/diameter is equal are equally difficult to sterilise, hence hollow devices would be all the more difficult to sterilise, the smaller their internal diameter. But this is true only subject to certain conditions. It has been reported that hollow devices are all the more difficult to sterilise, the greater their internal diameter. Furthermore, experiments have demonstrated that the steam penetration characteristics of hollow devices are a function of the material of which they are composed, of the wall thickness and, to a large extent, of the speed of the process, while it is not yet clear whether it is the

rate of pressure change or the related rate of temperature change that is decisive here.

To what extent the standard PCD featured in EN 867-5 is representative of medical devices with gaps and hollow cavities has thus not yet been ascertained. What is important here is that in everyday practice it is packed products that are being sterilised, and experiments have demonstrated that it is often essentially more difficult to sterilise packed hollow devices than unpacked hollow devices. And finally the steam penetration characteristics of hollow devices are largely dependent on the load configuration and on the orientation of the hollow device, also in the case of prevacuum processes and of processes with multiple pressure changes.

Hence, in principle, the hollow device as per EN 867-5 with an indicator system is merely a chemical indicator or a PCD. Even if this PCD is used for the type test, the use of such a device to test a process is not a substitute for performance qualification of the respective process during validation.

This chemical indicator can also be used for batch monitoring. But this is permitted only if it can be demonstrated during validation that the device when used in real-life configurations will detect an error before it can be spotted in the load.

As such, EN 285 needs to be amended with prEN 285-A1, but I expect that this merely represents the beginning of an ongoing trend. ♦