

# ISO 11140-1:2005

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The original version of ISO 11140 was published in 1995. It was being developed at the same time as the European Standard EN 867-1, however the European standard was not published until 1997. The Vienna Agreement is an agreement on technical cooperation between CEN and ISO in 1991. This was invoked during the revision of ISO 11140-1 such that the revision was carried out at ISO level with parallel voting at CEN level. The revision of ISO 11140-1 was completed in June 2005 and was adopted by CEN as a ratified text at approximately the same time. This will result in the withdrawal of EN 867-1 and EN 867-2, and will be replaced by EN ISO 11140-1:2005.

Many of the requirements in the new version of the standard are similar to that previously published. Most of the changes were to remove ambiguity in the requirements. For Europeans, perhaps the most significant change is the way classes of chemical indicators are described. EN867 referred to classes by way of an alphabetical system (A, B, C, D), whereas EN ISO 11140-1:2005 uses a numerical system (1, 2, 3, 4, 5, 6). This classification has two additional classes compared to EN 867-1, class 5 (integrating indicators) and class 6 (emulating indicators). The requirements and performance of class 6 indicators has not changed significantly since the 1995 version, although the requirements for class 5 indicators have

been changed to more closely resemble the performance of biological indicators, although this has meant a widening of tolerances for class 5 indicators.

EN867-1 did not contain test equipment or methods for characterising chemical indicators. ISO 11140-2 did contain this information, however it was agreed that there should be common test equipment for characterising both chemical and biological indicators. This has resulted in a draft standard ISO 18472, which should be published later in 2006. ISO 18472 will contain requirements for test equipment, with the respective test methods being stated in the relevant chemical indicator (ISO 11140) or biological indicator (ISO 11138) standards. ■

## 2. Schweizerische Fachtage über die Sterilisation



Schweizerische Gesellschaft für Sterilgutversorgung  
Soci t  Suisse de St rilisation Hospitali re

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