

Recommendations by the Quality Task Group (34): Packaging Part 3: Summary

Recommendations for hard packaging and soft packaging were published in editions 2 and 5 of *Central Service* 2003. Recommendation No. 30 pointed to the third section on the topic of packaging which is now printed here.

The tables on the diverse packaging materials contain information on validation, among other things. To clarify remarks relating to validation, in particular of sheet material, we wish to state:

A reproducible process for using sheet material can be assumed if, while taking account of the manufacturer's instructions, proper and expert use has been documented in standard operating procedures (SOPs).

Manual processes, which thus depend on the user's skills and motivation, do not meet the provisions of the German Medical Devices Operator Ordinance (MPBetrV) or the guidelines of the Robert Koch Institute (RKI).

Self-seal packing processes cannot be validated since such processes are not reproducible.

In this context it must be pointed out that neither cotton nor other → **TEXTILES** that do not bear a CE mark are classified as sterile supply packaging. At most, these can be placed as an internal wrap within primary packaging (see DIN 58953, Part 7-9).

To date, we are not aware of any expert opinions on the suitability of microfibres or laminated materials for use as sterile supply packaging, hence no recommendation can be given here.

The same holds true for other packaging materials used for medical devices.

In the Central Sterile Supply Departments (CSSDs) it will be scarcely possible to dispense with any of the packaging systems available. In → **PRACTICE**, hard and soft packaging (transparent packaging and sheet material) is used in parallel.

The composition of the medical devices to be packed, user requirements, structural features of sterile supply and transportation logistics are also decisive when choosing packaging.

Hence no general assessment can be made.

The valid standards can serve as a guide to decision-making and for evaluation purposes for users in the CSSD. → **EN 868**, Part 1 describes fundamental requirements for packaging, while the subsequent Parts 2–10 define requirements for the respective packaging systems.

The International Standardisation Organisation ISO has accepted that a general revision of ISO 11607 and EN 868 will be carried out under the direction of ISO, the intention being to set a globally uniform packaging standard. The new → **HARMONISED STANDARD** will consist of two parts:

- Part 1: Requirements for materials and packaging.
- Part 2: Requirements for sterile barrier systems, validation and assembly

This standard will be valid for all healthcare establishments and thus also for a hospital CSSD.

It is recommended that each CSSD has at their disposal, at least, the actual standards, e.g. the ones listed in the appendix to the RKI recommendation "Requirements for hygienic processing of medical devices" (<http://www.rki.de/GESUND/HYGIENE/ANFORDHYGMED.PDF>), or other national guidelines.

Parts 1 and 2 on the topic of packaging were published in editions 2 and 5/2003 of Central Service

→ **IF TEXTILES** are to be used, their suitability as sterile supply packaging has to be proven.

→ **IN PRACTICE**, hard and soft packaging is used in parallel.

→ **EN 868** outlines requirements for packaging.

→ **A HARMONISED PACKAGING STANDARD**, which is to be globally uniform, will be set on the basis of existing standards EN 868 und ISO 11607.