Packaging labelling and preparation process documentation

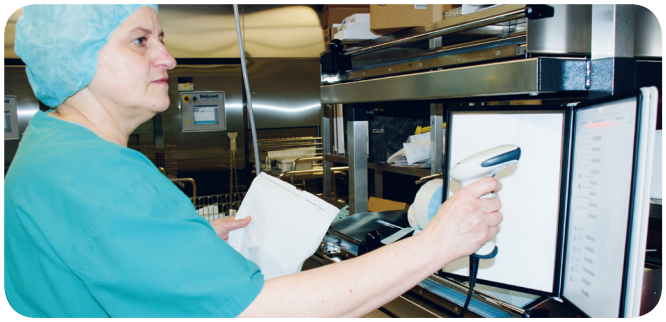
In general, information should be added to medical devices that ensures safe handling. In this regard, the following information should also be recognisable to the user at all times:

- LOT number
- Sterilisation date and type of sterilisation
- Expiry date and/or sterile product storage period (if this is shorter than the expiry date)
- Designation of the medial device

In addition, the approval decision for storage after sterilisation should also be visible on the packaging.

The new hawo VeriDoc® labelling and documentation system *(see advertisement)* enables you to meet labelling requirements, document the approval decision on the packaging as well as document the instruments used in the patient file. Regardless of whether it's sealable pouches and reels, wrappable sterilization sheets or reusable containers, the new system enables the labelling and integration of all available ready-made sterile barrier systems.

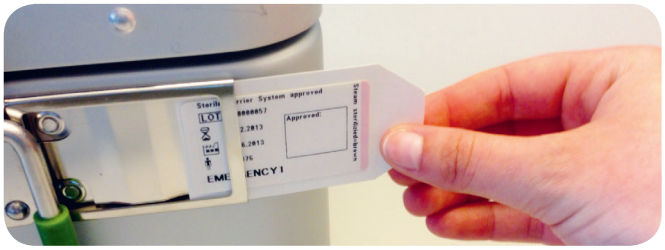
Using the included software, so-called 'scan lists' are first generated on a PC. First and foremost, these lists contain the names or personnel numbers of the authorised packagers. In addition, all available instruments, sets or containers are also included with their names or designations. A barcode is automatically assigned to each item or set on the list. The lists are then printed on any commercially available printer and made available to the user in the CSSD at the packaging location *(see picture 1)*. Additional information such as the size of the pouch, sterilisation sheet or container can also be directly added so that a suitable sterile barrier system is always used. This process only has to be performed once for the initial installation. For daily use, an additional computer is no longer required.



When the work process is started, the user first scans his name. Then the designation of the item or set to be packaged is scanned. The system now knows what should be packaged and by whom. In addition, you also have the option of assigning an individual expiry date to the packaging. This is especially important when event-related expiry dates have been defined by the operator. After successful packaging (sealing, wrapping or closing of reusable containers), the sterile barrier system undergoes a visual inspection. This includes checking the quality properties listed in ISO 11607-2 such as making sure there are no punctures or tears, no open seals or that there is a continuous closure for containers.

After a successful visual inspection, an approval barcode is scanned. The system then automatically prints a label with the corresponding identification information as well as the ID of the packager. If during the visual inspection it is determined that something is not right, then the 'sterile barrier system not approved' barcode must be scanned. The packaging can now be labelled with a 'do not use' label and separated accordingly. Unapproved sterile barrier systems may not be put into circulation. The label also has a class 1 process indicator as well as a separate field for the approval decision after sterilisation.

The labels are now put onto the packaging *(see picture 2 and 3)*.



After sterilisation is complete, the process indicator integrated on the label changes colour to indicate that the packaged instrument, set or container has undergone sterilisation. The corresponding LOT number of the sterilisation process carried out can be supplemented and the sterilised sterile barrier system can be approved for storage in the field assigned for this purpose. After treatment or operation, the so-called duplex labels can be easily removed from the sterile barrier systems (sealed pouch, wrapped set or container) and placed in the patient file as a corresponding appendix. Thus it is clear for each instrument, set or container used that it was packaged, underwent a sterilisation process, visually inspected and approved. When using medical instruments, a second check should also be made to ensure that the sterile barrier system is intact and/or has been sealed correctly. The written approval can also be performed in the appendix to the patient file.

The guidance document ISO/DTS 16775 requires that quality properties should be checked with an appropriate system and recommends commercially available dye penetration test kits or other seal indicators (e.g. Seal Check).

Before performing this test, the barcode on the Seal Check or dye test can be scanned. The system then automatically prints a label with the relevant test information such as test date, time, ID of test person as well as instrument identification. After comparing the seal check with a reference card *(see picture 8)*, the test can be approved directly on the label with a signature, and this can either be placed directly in the test system or documented in a separate list.

hawo GmbH