Recommendations by the quality task group (108)

Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2

Authors: D. Diedrich, A. Johmann, B. Amann, U. Zimmermann, T. Gerasch, A. Heidmann, R. Thomann, M. Kamer, M. Schreiner, S. Krüger, M. Bertram

qualitaet@dgsv-ev.de

Recent amendments to EN ISO 17664

Legal regulations applicable in the event of no or deficient processing instructions

Based on German legislation, the KRINKO/BfArM Recommendation [1] "Hygiene requirements for medical device processing" stipulates that when purchasing medical devices it should be borne in mind that the manufacturer must provide information on processing (KRINKO/BfArM Recommendation, Section 1.2.2). The recommendation explicitly states that this information must be supplied already at the time of **PROCUREMENT OF MEDICAL DEVICES**.

THE ACCURACY OF THE MANUFACTURER'S instructions should be verified already at the time of procurement of medical devices.

Any deviations from the manufacturer's processing instructions must be explained and documented. Attention must be paid here to risk factors such as e.g. functionality, application safety and effectiveness. In the event of any deviations testing and validation of the suitability and effectiveness of the processes chosen should be agreed with the infection control personnel.

In Germany, If no, or only incomplete, processing instructions have been supplied it may be necessary in an individual case to check whether this constitutes an incident pursuant to Section 2(1) MPSV [2] and therefore has to be notified as per Section 3(2) MPSV to the BfArM [3]. It is no doubt advisable to try to contact the manufacturer beforehand to directly resolve the matter.

If the issue cannot be resolved, incidents occurring within Germany can be notified to the BfArM by downloading a form on its website at "www2.bfarm.de/medprod/mpsv".

ESTABLISHMENTS WITH MORE THAN 20 EMPLOYEES must appoint a medical device safety officer.

Establishments with more than 20 employees must appoint a **MEDICAL DEVICE SAFETY OFFICER** (MPBetreibV, Section 6) who acts as contact person in matters related to notification of medical device risks to the authorities, manufacturers and suppliers and bears responsibility for implementation of the necessary remedial measures.

Pursuant to MPSV, the responsible person (in this case the processor) is obligated to notify incidents within 30 days of knowledge thereof. In this regard attention must also be paid to the instruction autonomy of the persons responsible for the maintenance of medical devices (MPBetreibV Section 7(4) [4]).

Procurement of medical devices

Pursuant to the KRINKO/ BfArM Recommendation (Section 1.2.2 Information to be Supplied by the Manufacturer), the accuracy of the manufacturer's instructions should be verified already at the time of procurement of medical devices. To that effect it is therefore advisable that all relevant parties should play a role in the procurement process. In that way the needs of users can be taken into account just like those of the purchasing department and compatibility of the medical devices with the available processing methods can be confirmed.

Recommendation 46 of the Quality Task Group features a checklist of which a revised version is now presented below.

References and abbreviations

1. KRINKO/BfArM Recommendation: "Hygiene requirements for medical device processing"
2. MPSV – Regulation on documentation, evaluation and prevention of risks related to medical devices (Medical Devices Safety Ordinance – MPSV)
3. BfArM German Federal Institute for Drugs and Medical Devices
4. MPBetreibV – Regulation on the installation, operation and use of medical devices

Checklist for procurement of new medical devices based on EN ISO 17664			
Device	Manufacturer's address		
Article No	Contact person TEL.		
Reason/application area/discipline	FAX		
Information required	YES	NO	Description available
Declaration of conformity/certificate			
Processing instructions			
Validation /test reports			
Article list /catalogue of accessories			
Information required	YES	NO	Description available
Dismantling/assembly required			
Maintenance intervals/tests required			
Restricted processing? (max cycles)			
Automated disinfection possible at 93°C			
Automated chemo-thermal disinfection possible			
Special cleaning adapters required			
Manual processing required			
Alkaline processing possible			
Positioning aids required			
Special requirements for packaging			
Special care agents required			
Steam sterilization at 121°C 18 min			
Steam sterilization at 134°C 5 min			
Formaldehyde sterilization			
Ethylene sterilization			
Plasma sterilization			
Replacement during repair possible			
Provision of sample possible			
Company seal	Signature		