

Recommendations by the Quality Task Group (31): Updating the Decision Tree on Risk Assessment and Classification of Medical Devices

Following publication of the Recommendation of the Robert Koch Institute (RKI) and of the German Federal Institute for Drugs and Medical Devices (BfArM): "Hygiene requirements for processing medical devices" (Federal Gazette 44 of November 2001), the "Quality Task Group" of the DGSV (German Society for Sterile Supply) compiled a → **DECISION TREE ON RISK ASSESSMENT** and classification of medical devices. This practical aid was presented for the first time at the DGSV congress in October 2002.

→ **FIRST DECISION TREE** in October 2002

We were able to present the → **NOW-REVISED DECISION TREE** to delegates attending this year's DGSV congress, which took place on 3 and 4 October. Already the original form of this decision tree, which is an illustration of Table 1 taken from the annex to the Recommendation and is presented as a flow chart, elicited the interest of many specialists dealing with medical device (MD) processing. However, while using this it became clear that there was a need to make changes, so that the content of the guideline could be properly presented, while ensuring that this tree could be used in daily routine practice.

→ **REVISED** in October 2003

These amendments related to the classification of → **CRITICAL GROUP A MDs**. According to the Recommendation, it is possible to use here not only final steam sterilisation (as depicted hitherto in the flow chart), but also a validated low-temperature sterilisation process for sterilisation of heat-sensitive MDs.

→ **CRITICAL GROUP A MDs** can be sterilised using a validated low-temperature sterilisation process.

As far as routine practice in the CSSD (Central Sterile Supply Department) is concerned, this means that heat-sensitive MDs can continue to be processed by an accredited external contractor without certification of the department. However, this applies only for those MDs for which no special processing requirements apply. In essence, these are all heat-sensitive MDs that have no lumens or poorly accessible sites. Examples of such devices are heat-sensitive cables and probes that are used in a sterile condition. For processing → **HEAT-SENSITIVE MEDICAL DEVICES OF CRITICAL GROUP B**, assignment to Critical Group C continues to apply. External certification of the CSSD (as per DIN EN ISO 13485/13488) is required for processing these MDs.

→ **HEAT-SENSITIVE CRITICAL GROUP B MDs** are classified as Critical C. To be processed only in an externally certified CSSD.

Following publication of the accreditation guidelines, the necessary accreditation of the certification bodies by the ZLG (Central State Body for Health Protection with Regard to Drugs and Medical Devices) is expected.

We must wait and see how many departments will opt for certification. Regardless of this, it recommended that a → **QUALITY MANAGEMENT SYSTEM** be set up and implemented in the CSSD; this is also specified in the RKI Recommendation.

→ **QUALITY MANAGEMENT** is of paramount importance in the CSSD, so as to furnish proof that MDs have been processed in line with the dictates of quality assurance.

This is the only means of furnishing proof that processing procedures have been carried out in line with the dictates of quality assurance, thus guaranteeing that perfectly sterile medical devices are used for the patient.

Note: the updated decision tree was printed in Number 5/2003.