Recommendations by the Quality Task Group (46) Manufacturer’s Instructions for Decontamination

Time and again users complain that the manufacturers of medical devices (MDs) do not provide any information on decontamination, or that if such instructions are given they are incomplete or of no use.

At this year’s congress of the German Society of Sterile Supply (DGSV), the Quality Task Group (AKQ) has organised a workshop on this topic to discuss the reasons for, and implications of, this state of affairs and to try to find a solution.

The ➜ **REQUIREMENTS TO BE MET BY THE MANUFACTURERS** or by those placing MDs on the market for the first time are set out in detail in the German Medical Devices Act (MPG). It must be assumed that the manufacturers who are based in Europe are conversant with the legal situation. And the authorised representatives of foreign manufacturers are expected to familiarise themselves with the legal stipulations and the decontamination methods applicable in German hospitals and in the reprocessing contractors’ establishments. The German Medical Devices Operator Ordinance (MPBetreibV) and the recommendation drafted by the Commission at the Robert Koch Institute (RKI) and at the Federal Institute for Drugs and Medicinal Products (BfArM) cite the German Medical Devices Act (MPG). The standard DIN EN ISO 17664 gives a detailed description of the instructions to be provided to the users.

➜ **THE REQUIREMENTS TO BE MET BY THE MANUFACTURER** are set out in the German Medical Devices Act (MPG) and are cited in the Medical Devices Operator Ordinance (MPBetreibV) and in the recommendation drafted by the RKI and BfArM.

Provisions of the German Medical Devices Act*

Section 5 states that the manufacturer/his authorised representative or the importer bears responsibility ➜ **THE FIRST TIME THE MEDICAL DEVICE IS PLACED ON THE MARKET**. The name, company name and address must be featured in the MD designation or in the operating manual. These data are forwarded to the German Institute for Medical Documentation and Information (DIMDI) for central processing and utilisation.

➜ **FOR THE FIRST TIME THE MEDICAL DEVICE IS PLACED ON THE MARKET** the manufacturer or the importer bears responsibility.

Section 25 (1and 2) focuses on monitoring, risk protection and on the general ➜ **NOTIFICATION OBLIGATION**. Accordingly, the person/institution bearing responsibility for the MD when it is first placed on the market must inform the competent authority of this beforehand and must assign a name to the MD. This also holds true for companies and establishments that reprocess medical devices for other parties. The MD designation must be included with this information.

➜ **AN OBLIGATION TO NOTIFY THE COMPETENT AUTHORITY** applies to the person/institution bearing responsibility for the MD when it is first placed on the market.

Anyone processing MDs that must be used in a sterile state after they are first placed on the market and handing them over to a third party, must carry out a conformity assessment procedure.

Section 26 deals with ➜ **MONITORING** of such establishments. The competent authority shall take any necessary measures for elimination of any documented infringements or for prevention of such.

➜ **MONITORING OF SUCH ESTABLISHMENTS** is effected by the competent authority.

Pursuant to Section 31, the medical devices’ consultant must have the requisite expertise and experience as regards the respective MD. He is obliged, as stipulated in Section 29, to record in writing and report e.g. malfunctions, technical drawbacks, etc.

Annex I to MPG stipulates the ➜ **INFORMATION TO BE PROVIDED** by the manufacturer. Item 13.6 h states that in the case of reusable MDs instructions must be given on suitable decontamination processes, e.g. on cleaning, disinfection, packing, and on sterilisation, if applicable, as well as on any restriction on the total number of times a MD may be reprocessed.

➜ **INFORMATION ON SUITABLE DECONTAMINATION PROCESSES** has to be provided by the manufacturer.

DIN EN ISO 17664

This standard is a source of help to MD manufacturers by providing a ➜ **MATRIX** into which the most important specifications for MD decontamination can be entered. Many users would welcome more concrete specifications, in particular on automated decontamination.

➜ **A MATRIX** into which the most important specifications for MD decontamination can be entered is provided in DIN EN 17664.

* The authors intend this only as a brief overview and it is not a substitute for an in-depth study of the legal texts.

Purchasing List

Users have devised purchasing lists into which the in-house relevant data for any new MD can be entered before such an MD is purchased. This approach helps the purchasing department to make a decision in cooperation with the infection control team, clinicians and the CSSD.

→ **A PURCHASING LIST** into which the in-house relevant data can be entered before an MD is purchased has been devised by users.

To provide for correct decontamination and use of medical devices, we request the following details and associated documentation pursuant to DIN EN 17664.

Device designation:
Article No.:
Serial No., if applicable:

Manufacturer's address:
Medical device consultant:
Tel.:
Fax:

Information required	Available	Not required	Enclosed in Annex
Declaration of conformity/certificate			
Decontamination instructions			
Operating instructions or product description			
Validation or test report			
Article list of accessories			
Material for training (CD-ROM, if possible)			
Repairs reference list			

Information required	Yes	No	Description given in decontamination instructions
Dismantling or assembly needed for decontamination			
Maintenance or regular checks necessary			
Restriction on the number of times MD can be reprocessed			
Automated cleaning – thermal disinfection possible at 93 °C			
Automated cleaning – chemical/thermal disinfection possible			
Manual cleaning needed			
Immersion disinfection possible			
Wipe disinfection needed			
Ultrasonic decontamination possible			
Use of alkaline cleaning possible			
List of suitable detergents and disinfectants available			
Exclusion of certain chemicals (e.g. softeners) applicable			
Storage tips needed for decontamination and transport			
Special requirements for MD packaging			
Care agents needed			
Autoclavable at 134 °C			
Autoclavable at 121 °C			
Formaldehyde sterilisation			
Ethylene oxide sterilisation			
Plasma sterilisation			
Replacement during repair possible			
Provision of sample possible			

Company seal: **Signature:**