Recommendations by the quality task group (108 – update)

Information to be provided by the medical device manufacturer for the processing of medical devices – Checklist updated

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The second part of the recommendation "Information to be provided by the medical device manufacturer" pointed out that the accuracy of the manufacturer's instructions should be verified already at the time of procurement of medical devices.
It has been pointed out that, ideally, all relevant parties should play a role in the procurement process. Only 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.
A checklist was provided with Recommendation 108 to support the assessment of all influencing factors in the processing of the newly procured medical device. In the meantime, there have been some comments and suggestions for improvement of this checklist from the readers, which have prompted us to publish an update of the checklist.
Please use this revised version of the checklist in the future. It is coordinated with representatives of the AKI, among others, and will certainly provide useful support to the procurement process.
You can also download the checklist from the DGSV e.V. website.

Checklist for procurement of new medical devices based on EN ISO 17664			
Device	Name and address of manufacturer/provider		
Article No	Contact person TEL.		
Reason/application area/discipline	FAX E-mail		
Information required	YES	NO	Description available in
Declaration of conformity/certificate available?			
Processing instructions available?			
Has the process indicated by the MD manufacturer been validated?			
Article list/catalogue of accessories available?			
Information required	YES	NO	Description available in the instructions for use (IFU) or in (please state)
Dismantling/assembly required?			
Maintenance intervals/tests required?			
Restricted processing (max cycles)?			
Automated cleaning and disinfection possible at 93°C?			
Automated cleaning and chemo-thermal disinfection possible?			
Alkaline cleaning possible?			
Neutral cleaning required?			
Special cleaning adapters required?			
Positioning aids required?			
Special care agents required?			
Special requirements for packaging?			
Steam sterilization at 121°C 20 min?			
Steam sterilization at 134°C 5 min/18 min?			
Formaldehyde sterilization?			
Ethylene oxide sterilization?			
H_2O_2 sterilization processes?			
Other sterilization processes?			
Terminal disinfection – sterilization not required?			
Replacement during repair possible?			
Provision of sample possible?			
Company seal	Date Signature		