Notwendige Korrektur des Flussdiagramms der DGSV 2012 im Januar 2013

In der Ausgabe 6/2012 der *Zentralsterilisation* wurde die Empfehlung 77, das überarbeitete Flussdiagramm der DGSV zur Einstufung von Medizinprodukten, veröffentlicht. Zum großen Bedauern der Verfasser wurde im Flussdiagramm an einigen Stellen unklar formuliert. Dadurch kann es zu Diskussionen, insbesondere zum Thema «Validierte Verfahren» kommen. Deshalb wurden Korrekturen vorgenommen, und das Flussdiagramm wird erneut mit der Überschrift «Flussdiagramm der DGSV zur Einstufung von Medizinprodukten 2013» veröffentlicht. In der Überarbeitung wurde der Begriff «validiert» aus dem Flussdiagramm gestrichen und stattdessen wurde auf dem Merkblatt «Ergänzende Informationen zum Flussdiagramm zur Einstufung 2012» ein weiterer Merksatz zu «Geeigneten validierten Verfahren» vorangestellt.
Wir bitten alle Leser der *Zentralsterilisation* und alle Besucher der Webseiten, die Empfehlung aus der *Zentralsterilisation* Heft 6/2012 durch die aus der Ausgabe 1/2013 zu ersetzen.

Correction Needed to DGSV Flow Chart 2012 in January 2013

In Issue 6/2012 of *Central Service*, Recommendation 77, the revised version of the DGSV flow chart for classification of medical devices, was published. The authors very much regret that the wording used in certain sections was unclear. That gave rise to discussions, in particular on the topic of «validated processes». Therefore corrections have been made and the flow chart is being published again under the title «DGSV Flow Chart 2013 for Classification of Medical Devices». The term «validated» has been deleted from the flow chart and instead an additional key sentence on «Suitable validated processes» has been added to the instructions' sheet. We ask all readers of *Central Service* and all website visitors to replace the Recommendation from Issue 6/2012 with that from Issue 1/2013.

Recommendations by the Quality Task Group (77 Revised Version)

DGSV Flow Chart 2013 for Classification of Medical Devices

With the publication of the recommendation by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the hygiene requirements governing the reprocessing of medical devices (KRINKO/BfArM Recommendation) in the Federal Health Gazette 2012; 55:1244–1310 it became necessary to revise the flow chart compiled by the German Society of Sterile Supply (DGSV) for classification of medical devices. During the revision process it was noted that certain parts of the flow chart had to be explained and that a supplement should be provided in addition to the diagram in order to establish a direct link to some of the citations from the KRINKO/BfArM Recommendation. Apart from comments explaining certain points, this Recommendation does not constitute a statement of opinion by the Quality Task Group of the DGSV e. V. on the contents of the KRINKO/BfArM Recommendation.
The flow chart and instructions' sheet are intended as a means of making it easier for users/reprocessing personnel to classify medical devices before reprocessing. The use for which medical devices are intended is specified in the manufacturer's instructions (e. g. minimally invasive surgery [MIS] instruments, cystoscopes, hysteroscopes, spinal cord instruments, ear, nose and throat [ENT] instruments, eye instruments, endoprosthetic instruments). Hence how a medical device is to be used is always a basic prerequisite to be borne in mind for risk assessment and classification. That means that a device can be properly classified only after consulting users, or the person responsible for classification has the necessary knowledge of the intended use thanks to his aptitude/qualification and expertise. Only in this way can the medical device circuit function and proper reprocessing be assured.
The publication was agreed in advance with representatives of the RKI and a link to it is given on the RKI website. The DGSV Quality Task Group hopes that this revised flow chart, too, will prove to be a useful recommendation for classification of medical devices. It replaces Recommendations 22, 23 and 24 on classification of medical devices prior to reprocessing (Parts 1 – 3) published in 2002, Recommendation 31, update of decision-making tree on risk assessment and classification of medical devices published in Issue 6/2003 as well as the publication that was compiled in 2008 in A3 format together with DIOS.

Instructions; sheet «Supplementary information on the Flow Chart 2012 for classification of medical devices»

Suitable validated processes

Page 1265, **Annex 1**: «*For decontamination of a medical device, the sum of all the automated and manual processes involved (individual decontamination steps that complement each other) contribute to reaching the respective decontamination goal. Hence, inadequately validated individual steps (processes) detract from the quality of the decontamination results in equal measure as the failure to observe standard operating instructions*.»
Page 1250, **1.3 Validation of decontamination processes**: «*When choosing cleaning and disinfection processes, priority must be given to automated processes that can be validated. Manual cleaning and disinfection processes, which for example are used to preclean medical devices or to clean/disinfect those medical devices not amenable to automated decontamination (group B) or which are employed on the basis of risk analysis, must always be carried out in accordance with standard operating procedures, using products and processes whose effectiveness and compatibility with the respective medical device has been verified (i. e. which are suitable and compatible with the respective material)*.»
As such, all individual steps, both manual and automated steps, must be taken into account when validating the decontamination process.

*(*1) Manufacturer's instructions for reprocessing*

Page 1250, **1.2.2 Manufacturer's instructions**: «*The marketability of a medical device classified by the manufacturer for reuse implies that the manufacturer is obliged to provide instructions for reprocessing, including for cleaning, disinfection, rinsing, drying and, if applicable, for packing and sterilization, transport as well as proper storage and, if applicable, also regarding the risks associated with reprocessing*» … «*If there is any deviation from the manufacturer's reprocessing instructions, the reason for this must be explained and documented, while ensuring that the functional capability, as specified by the intended use, and the application safety of the reprocessed (decontaminated) medical device are fully preserved (see also 1.2.1). Appropriate testing and validation of processes, which take account of the medical device and its risk assessment and classification, must be carried out to ascertain their suitability and effectiveness in collaboration with infection control (hygiene) personnel*.»
This entails extensive testing, in particular for critical medical devices, which is generally beyond the scope of a reprocessing unit (reprocessing centre). At this juncture, it is also advisable and/or necessary to decide against reprocessing of the medical device.

*(*2) Expert personnel*
Page 1276, **Annex 6, Expertise of personnel**: «Requirements regarding the expertise of personnel entrusted with reprocessing in Category A and B reprocessing units» (see Annex 5)
Page 1275, **Annex 5, Overview of requirements addressed to medical devices reprocessing units**: Category A, B and C reprocessing units with regard to classification of the medical devices to be decontaminated
Reprocessing Unit A = Semi-critical A, critical A
Reprocessing Unit B = Semi-critical B, critical B
Reprocessing Unit C = Critical C (includes A and B)

*(*3) «Blood products» are not mentioned in Flow Chart 2012*
Page 1247, **1.2.1 Risk assessment and classification of medical devices before reprocessing**: «*Medical devices for application of blood, blood products or other sterile drugs/sterile medical devices …*» are critical medical devices and must be classified and decontaminated according to the information provided in the flow chart.

*(*4) Precleaning*
With regard to reprocessing after use, the following point must be noted:
Page 1252, **2.2.1 Preparations for reprocessing (pretreatment, collection, precleaning, if applicable, dismantling, intermediate storage and transport)**: «*To avoid compromising the hygienic state and the functionality of the decontaminated medical device, in particular if there are any delays before cleaning and disinfection, precleaning and, possibly, intermediate storage is needed and must meet the following requirements:*

– *Coarse soils should be removed from the medical device immediately after use. Every effort must be made to identify suitable methods and procedures to prevent blood and tissue from drying onto the medical device (e.g. by wiping off external soils and rinsing working channels immediately after use; devising a schedule to collect instruments after use), and especially to avoid any negative impact on the cleaning performance (drying of pathogens in protective colloids) …*»

Standard operating procedures (SOPs) must be compiled as part of the quality management system for those process steps conducted outside the reprocessing unit. These must be jointly drafted by users and reprocessing personnel.

*(*5) Protective packaging for disinfected devices*
Page 1256, **2.2.6 Labelling**: «*In the case of medical devices for which reprocessing ends with disinfection, the user must also be able to recognize that the process has been executed (QM).*»
Page 1258, **3 Transport and storage**: «*(Semi-critical) medical devices harbouring only a low microbial count must be stored such that recontamination is avoided during storage*»
Packing and labelling are implemented using appropriate protective packaging in the clean zone of the reprocessing unit, while avoiding recontamination, in a dry state and with personnel wearing gloves that harbour at most only a low microbial count.

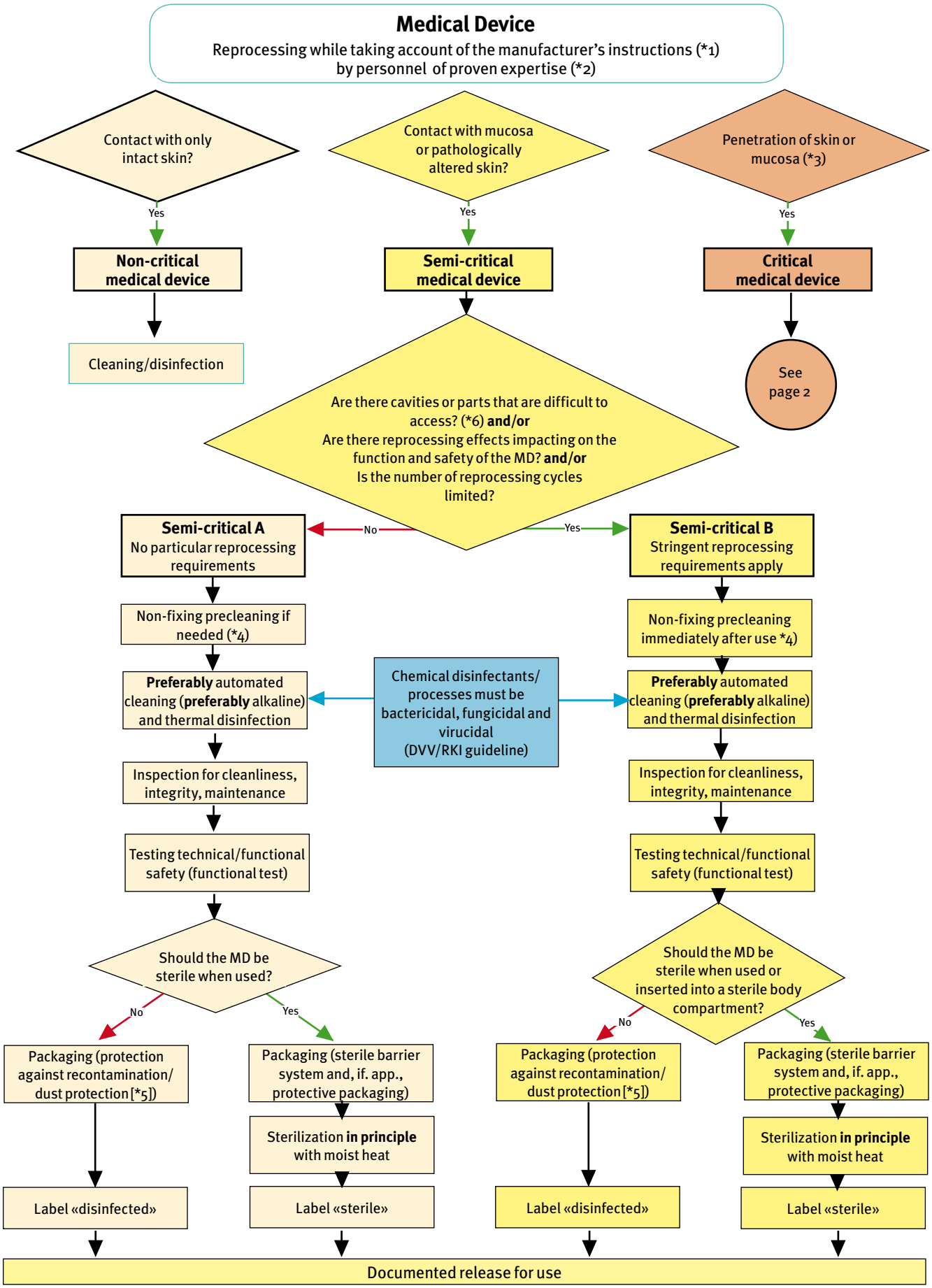
*(*6) Wording «cavities or parts that are difficult to access»*
In the flow chart the wording «cavities or parts that are difficult to access» was retained to make this easier to understand. The wording in the KRINKO/BfArM Recommendation is as follows.
Page 1248, **1.2.1 Risk assessment and classification of medical devices before reprocessing**: *The aforementioned wording «cavities or parts that are difficult to access» is understood to mean those medical devices for which «the effectiveness of cleaning cannot be assessed through visual inspection (e. g. because of long, narrow, and especially lumens closed at one end, cavities with only one opening [purging is not possible, only dilution], surfaces that are complex, rough or poorly accessible and therefore difficult to clean).*»

*(*7)Disinfection A_0 value*
Page 1254, **2.2.2 Cleaning, disinfection, rinsing and drying**: «*Preference must be given to thermal processes in washer-disinfectors because of their superior reliability (e. g. less risk of residual contamination) over chemical or chemothermal processes.*»
For the A_0 value concept please refer to EN ISO 15883-1 and to the Guideline for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices and for selecting washer-disinfectors, Annex 7: The A_0 concept of EN ISO 15883.

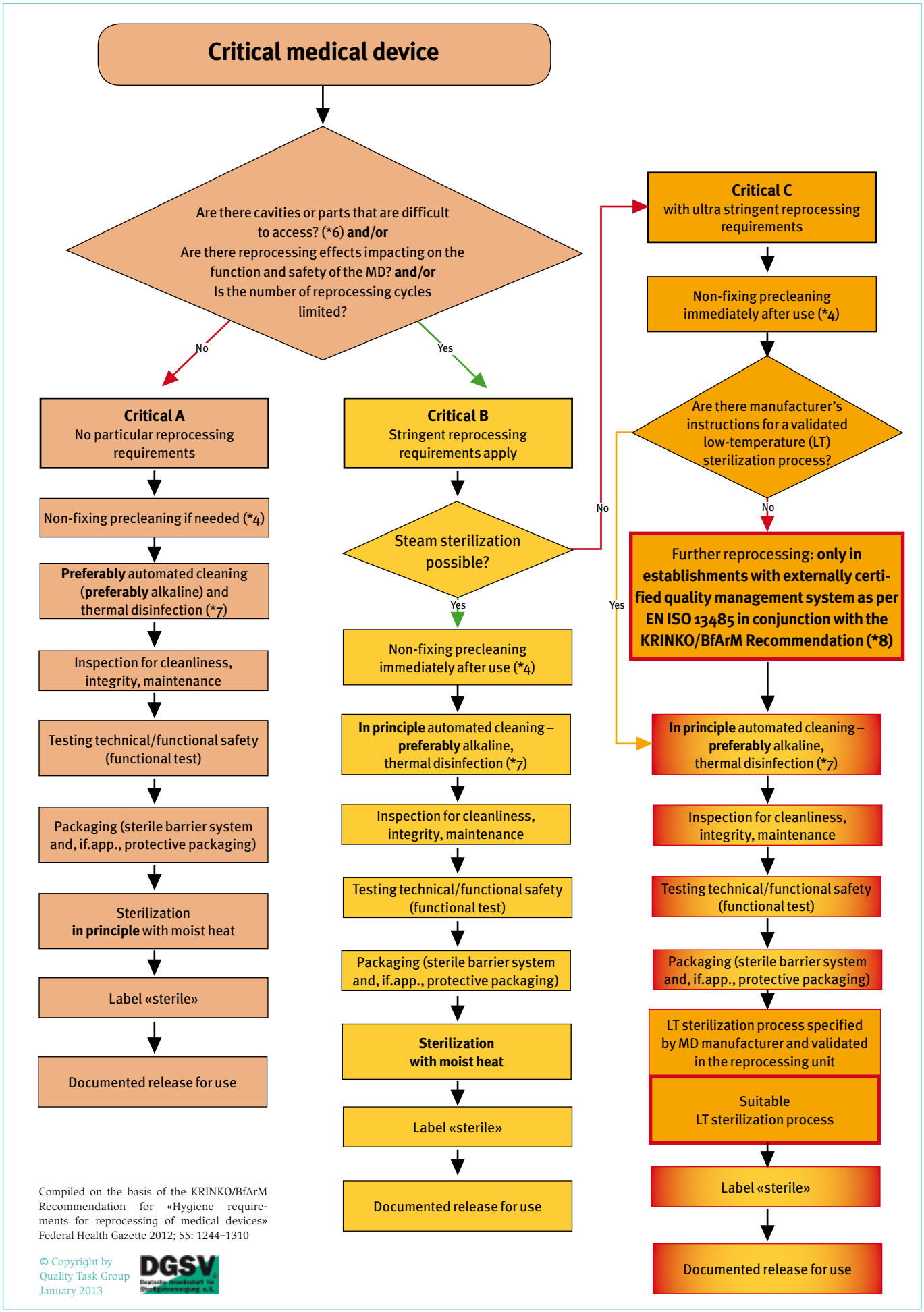
*(*8) Certification – reprocessing of category Critical C medical devices*
Page 1247, **1.2.1 Risk assessment and classification of medical devices before reprocessing** and Page 1251, **1.4 Safeguarding the quality of the reprocessing processes used**: «*Reprocessing of medical devices subject to ultra stringent reprocessing requirements («critical C», see . Table 1) shall be certified pursuant to EN 13485 by a body accredited by the competent authority in conjunction with their «Hygiene requirements for reprocessing of medical devices» (QM). … External certification is not required if the manufacturer of the medical device has specified concrete instructions for using another special sterilization process and the application of that process has been validated in situ in terms of its effectiveness.*»
The expression «another special sterilization process» means a process other than moist heat sterilization.

Reprocessing of «non-medical devices»
Foodstuffs utensils, e. g. baby bottles, pacifiers, drinking cups, etc. are generally not medical devices and are not subject to classification as per the KRINKO/BfArM Recommendation. They are decontaminated in accordance with other guidelines or/and recommendations of specialist societies.

DGSV Flow Chart 2013 for Classification of Medical Devices



Compiled on the basis of the KRINKO/BfArM Recommendation for «Hygiene requirements for reprocessing of medical devices» Federal Health Gazette 2012; 55: 1244–1310



Compiled on the basis of the KRINKO/BfArM Recommendation for «Hygiene requirements for reprocessing of medical devices» Federal Health Gazette 2012; 55: 1244–1310