Customer information

General legal position for the reprocessing of medical devices

The reprocessing of medical devices was explicitly permitted from the date of the applicable German Medical Devices Act of 1 January 2002 at the latest. In this context, it should be noted that neither the German Medical Devices Act nor the European legislator differentiates between so-called multiple-use products and so-called single-use products in the reprocessing of medical devices. Rather, the sole distinction made is whether the medical device is able or unable to be reprocessed. When and under what conditions a medical device can be reprocessed is determined essentially by the recommendations for reprocessing medical devices of the Commission for Hygiene in Hospitals and Prevention of Infectious Diseases at the Robert Koch Institut and the Federal Institute for Drugs and Medical Devices (BfArM). These recommendations, which were made in 2001, were updated in October 2012. The new version of the reprocessing recommendations replaces the earlier version of 2001. The so-called "KRINKO-BfArM Recommendations" have particular significance through their referencing in the Medical Devices Operator Ordinance. According to the Medical Devices Operator Ordinance (Section 4, Article 2), for proper reprocessing to have been carried out, it is assumed that these shared recommendations have been observed.

Through the reference in the Medical Devices Operator Ordinance, this guideline has become applicable law. On the basis of this legal framework, it is possible to reprocess medical devices, if and in so far as the high technical and hygiene standards set out in the KRINKO guidelines are observed. In this context, we would like to take the liberty of expressly reiterating the fact that these guidelines apply to the reprocessing of both so-called single-use products and multiple-use products.

It follows necessarily from the foregoing that, as a user and operator of medical devices, you do not have to fear liability for having reprocessed these products or having had them reprocessed by an external provider. Rather, you would have to fear liability only if the reprocessing were not carried out in accordance with the relevant applicable standards of science and technology and under observance of the Acts and Regulations. Liability for you as a user and operator of (reprocessed) medical devices is therefore determined exclusively by the general principles. With the assurance that the devices it reprocesses are impeccably hygienic, sterile and comparable to new products, VANGUARD AG has created a comparable liability situation of statutory product liability. Therefore, if it is established that a medical device reprocessed by VANGUARD AG does not meet the aforementioned requirements and leads to a concrete damage event, VANGUARD AG, in its internal relationship with you as an operator and user of reprocessed medical devices, is liable **regardless of fault**. VANGUARD AG has liability insurance cover for possible risks in the amount of € 26,000,000.00.

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How does VANGUARD ensure cleanliness and safety in the reprocessing of medical devices?

The reprocessing of medical devices is carried out by VANGUARD using standardised and validated methods exclusively. VANGUARD AG's quality management system is certified according to DIN EN ISO 13485 and comprises the reprocessing of medical devices, including those classified as "critical C", in accordance with the Commission for Hygiene in Hospitals and Prevention of Infectious Diseases at the Robert Koch Institut and the Federal Institute for Drugs and Medical Devices (KRINKO recommendations).

The certification of a quality management system for reprocessing includes a formal inspection by an auditor and an inspection by subject-matter experts. For this additional examination, the accuracy of processes, including result quality, i.e. the hygienic innocuousness and functionality of the medical devices to be labelled, are inspected by one of the recognised subject-matter experts from the ZLG (Central Authority of the Länder for Health Protection). This also provides confirmation of quality and functionality for reprocessors by an examiner.

To attain a certificate, the reprocessor must prove both the quality management system, i.e.

- the totality of the quality-related activities and objectives
- general organisational and technical conditions
- organisational structure, level of training
- commercial relationships

as well as the technical accuracy of the reprocessing on labelled products, i.e.

- risk classification according to the RKI (Robert Koch Institut)
- consideration of the original manufacturer documentation
- risk management of the entire reprocessing process
- functional safety of all medical devices
- hygiene safety of all medical devices
- validity of all reprocessing methods with the preparation, cleaning/disinfection, inspection, packing, sterilisation and identification steps.

Only medical devices for which a successful validation is present are reprocessed. Along with inspections of the maintenance of functionality and hygiene safety in manufacturing, the validation also includes reprocessing frequency tests. Guidelines for the standardised reprocessing process are derived from the validation inspections and handed over to staff as instructions.

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VANGUARD handles all incoming medical devices as "critical C" products. Incoming medical devices are given a product identification number (product ID) through laser coding, thus guaranteeing 100% traceability and an illustration of the product life cycle. Products without manufacturer information and products that have obviously been reprocessed by others, e.g. the hospital itself or other providers, are excluded from reprocessing and are not released to be used again. Furthermore, every instance of non-fulfilment of a fixed product feature leads to automatic blocking of the product.

Appropriate checks and controls are provided for every reprocessing step. A product can only be passed on to the next step in the procedure after successful completion of this intermediate inspection. Overall, each individual medical device undergoes at least the following inspections:

- Initial inspection
- Plausibility inspection in at least 3 process steps with regard to correspondence with
- manufacturer and customer information
- Inspection of cleanliness and intactness in at least 3 process steps
- 100% specific functional inspection
- Inspection of the plausibility, completeness and accuracy of the predefined reprocessing steps as part of of the final check

These inspections are supplemented by

- 100% batch inspection of disinfection/cleaning
- 100% batch inspection of sterilisation

How does VANGUARD ensure the requirements in accordance with the Ordinance on Safety Plans for Medical Devices (MPSV)?

Vanguard AG has reported the reprocessing in accordance with the requirement of Section 25 of the MPG (German Medical Devices Act) and nominated a Medical Devices Safety Officer, in accordance with Section 30 of the MPG.

To fulfil the legal ordinance to be applied (ordinance for the registering, assessment and avoidance of risks for medical devices (Ordinance on Safety Plans for Medical Devices [MPSV]), the Safety Officer assesses each complaint and every other response relating to it. Each individual case is examined to establish whether there is an incident according to Section 2 of the MPSV. There has been no incident to date that can be attributed to inadequate reprocessing by Vanguard AG.

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In addition, information on risk is actively assessed at regular intervals by the BfArM. This concerns:

- manufacturers' methods,
- BfArM recommendation and
- scientific reappraisal

For products reprocessed by Vanguard AG, this information, in particular manufacturers' methods, are checked precisely up to batch and lot number. In the case of recalls by the manufacturer, the relevant products are excluded from reprocessing.

Supervision by the authorities

The supervisory authority responsible has carried out its tasks conscientiously from the beginning of Vanguard's activities.

Not a single case of improper reprocessing has been established to date in either announced or unannounced inspections.

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Please contact us if you have any further questions.