

Legal framework conditions for the reprocessing of medical devices

Rechtliche Rahmenbedingungen zur Aufbereitung von Medizinprodukten

Abstract

The processing of single-use products is permissible pursuant to medical device law. This is apparent both from the wording of the German Law on Medical Devices and from the purpose and the objectives underpinning the legislative materials. The prerequisite for processing is, however, compliance with the the Joint Recommendation of the Commission for Hospital Hygiene and the Prevention of Infection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Products (BfArM).

For medical devices in the category “critical C”, the RKI/BfArM-recommendation provides that the processor’s quality management system must be certified by a body accredited by the Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, ZLG). The certification must be carried out in accordance with EN ISO 13485:2003+AC:2007.

On April 4, 2008 the Federal Health Ministry (Bundesministerium für Gesundheit, BMG) presented a progress report on the processing of medical devices. The BMG concludes that the legal framework for the processing of medical devices is sufficient, and that a prohibition on the processing of single-use products is inappropriate.

Keywords: reprocessing, medical devices, certification, single-use product, DIN EN ISO 13485:2003+AC:2007, Federal Health Ministry, Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices, accreditation

Zusammenfassung

Die Aufbereitung von Einmalprodukten ist medizinprodukterechtlich zulässig. Das ergibt sich sowohl aus dem Wortlaut des Medizinprodukterechts als auch aus Sinn und Zweck und aus den Gesetzesmaterialien. Voraussetzung ist allerdings die Einhaltung der gemeinsamen Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention des Robert Koch-Instituts (RKI) und des Bundesinstituts für Arzneimittel und Medizinprodukte (BfArM).

Für Medizinprodukte der Kategorie „kritisch C“ sieht die RKI/BfArM-Empfehlung vor, dass das Qualitätsmanagementsystem des Aufbereiters durch eine von der Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukte (ZLG) akkreditierte Stelle zertifiziert sein muss. Diese Zertifizierung hat nach DIN EN ISO 13485:2003+AC:2007 zu erfolgen.

Das Bundesministerium für Gesundheit (BMG) hat am 04.04.2008 einen Erfahrungsbericht zur Aufbereitung von Medizinprodukten vorgelegt. Im Ergebnis stellt das BMG fest, dass der Rechtsrahmen für die Aufbereitung von Medizinprodukten ausreichend und ein Verbot der Aufbereitung von Einmalprodukten nicht sachdienlich sei.

Schlüsselwörter: Aufbereitung, Medizinprodukt, Zertifizierung, Einmalprodukt, DIN EN ISO 13485:2003+AC:2007, Bundesministerium

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Introduction

The term reprocessing is defined in § 3 No. 14 MPG (Medizinproduktegesetz) as follows: The reprocessing of medical devices intended to be applied semi-sterile or sterile, is the cleaning, disinfection and sterilisation, including the processes connected therewith, as well as the testing and restoration of technical-functional safety, following their use for the purpose of renewed use.

It clearly follows from this definition that the term “reprocessing” refers not only to the cleaning, disinfection and sterilisation of medical devices. Rather, the technical-functional safety must also be tested and, if necessary, restored. Reprocessed medical devices must offer the same standard of safety as a new product in terms of their material characteristics, their functions (e.g. recording, cutting, coagulating) etc.

At the same time, the legislator clarifies in § 4 para. 1 MPBetreibV (Medizinproduktebetriebsverordnung) that, in addition to servicing, inspection and repair, reprocessing constitutes a fourth sub-category of maintenance, and is thus recognised as another form of operation of medical devices.

There are currently approximately 400,000 medical devices on the market. A large number of these articles can – following appropriate professional reprocessing – be re-used in medical treatment.

Without a doubt, it is particularly health economics arguments that influence the decision as to whether to reprocess medical devices for re-use. The basic rule here is that reprocessing – regardless of whether a medical device is declared for single use or for repeated use – is even more worthwhile the greater the input of materials and resources required in the manufacture of the medical device in question.

This economic interest is, however, limited by the need to protect patients against functional, immunological, toxicological or hygienic impairment through reprocessed medical devices. In healthcare practice, this economic/legal conflict initially triggers questions in particular with regard to the regulatory aspects of Medical Device Law. However, medical liability law is also increasing in importance in this area.

Reprocessing requirements pursuant to medical device law

The regulatory requirements for reprocessing medical devices are set forth in the law on medical devices. The basic norm here is the German Act on Medical Devices (*Medizinproduktegesetz*, hereinafter MPG), which transposed Directive 90/385/EEC (active implantable medical devices), 98/79/EC (in-vitro-diagnostics) and 93/42/EEC (other medical devices) into German law.

The general provisions of the MPG are governed in detail in a number of ordinances, e.g. The Medical Device Operators Ordinance (*Medizinproduktebetriebsverordnung*, hereinafter MPBetreibV).

The requisite reprocessing quality is defined in § 4 para. 2 sentence 1 MPBetreibV.

The reprocessing of medical devices intended to be applied semi-sterile or sterile is to be carried out taking into account the manufacturer’s specifications using suitable validated procedures, such that the success of these procedures can be verifiably ensured and the safety and health of patients, users or third parties is not put at risk. § 4 para. 2 sentence 3 MPBetreibV governs when proper reprocessing, as defined in § 4 para. 2 sentence 1 MPBetreibV, is given:

Proper reprocessing pursuant to sentence 1 is assumed if the Joint Recommendation of the Commission for Hospital Hygiene and the Prevention of Infection at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices concerning Hygiene Requirements when Reprocessing Medical Devices is observed.

In terms of the law, a rule of assumption, which can be refuted in individual cases, was chosen ([1] Vol. 3, Chapter 8.4, 12f). If an operator or, as the case may be, an external processor (service provider), carries out the reprocessing in accordance with the Joint Recommendation of the Commission for Hospital Hygiene and the Prevention of Infection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Products (BfArM) (hereinafter: joint RKI and BfArM Recommendation [2]), then it shall initially be assumed that the reprocessing was carried out properly.

The Joint RKI and BfArM Recommendation

The Joint RKI and BfArM Recommendation governs the details concerning the hygiene requirements when reprocessing medical devices. Medical devices are divided into various categories of risk on the basis of the type of application, and the risk involved:

- non-critical medical devices (e.g. ECG electrodes),
- semi-critical medical devices (e.g. endoscope),
- critical medical devices.

Pursuant to the Joint RKI and BfArM Recommendation, critical medical devices are devices used for the application of blood, blood products and other sterile medicinal products and medical devices that penetrate the skin or mucous membrane and thereby come into contact with blood, internal tissues or organs, including wounds.

In turn, the critical medical devices are divided into sub-categories:

- critical A (without particular reprocessing requirements, e.g. hook retractors),
- critical B (with more stringent reprocessing requirements, e.g. MIC trocars),
- critical C (with particularly stringent reprocessing requirements, e.g. heart catheters).

The Joint RKI and BfArM Recommendation provides with regard to medical devices belonging to the category “critical C”, that the reprocessor’s quality management system must be certified by a body accredited by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (*Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukte*, ZLG; named body pursuant to § 20 para. 1 MPG). This certification must be carried out in accordance with DIN EN ISO 13485:2003+AC:2007, i.e. in accordance with the only DIN norm currently applicable in the area of Quality Management Systems of medical device reprocessing.

Accreditation and certification

Pursuant to the Joint RKI and BfArM Recommendation, not every body can certify the quality management systems for the reprocessing of medical devices belonging to the category “critical C”. Instead, a designated body (explanation: named bodies are independent certifying offices organised under private law. They are, however, subject to state supervision and must be accredited by the ZLG, for example. The suitability as a designated body is examined and ascertained in the accreditation proceedings) must be specifically accredited by the ZLG for this purpose. In contrast to the ZLG, the Central Authority of the Länder for Safety Technology (*Zentralstelle der Länder für Sicherheitstechnik*, ZLS) does not certify any appointed offices for the reprocessing of medical devices.

As per May 1, 2008 the following designated bodies have been accredited by the ZLG (<http://www.zlg.de>) for this purpose:

- DEKRA Certification GmbH Stuttgart,
- LGA InterCert Nürnberg,
- TÜV Rheinland Product Safety GmbH Köln,
- MedCert Hamburg.

Finally, it must be pointed out that the certificates issued by the accredited designated body have a limited applicability – they usually apply for a maximum of five years. This corresponds with the provisions in § 17 para. 1 MPG. Reprocessors must, as explained under point 2, prove their ability to properly reprocess medical devices belonging to category “critical C” as defined in § 4 MPBetreibV, by way of a certificate issued by a designated body accredited for this purpose by the ZLG.

The quality management system of the company for the reprocessing of medical devices belonging to the category “critical C” is tested in the course of such certification. This certification relates both to the introduction and to

the maintaining and application of the quality management systems.

The certificate is granted for specific groups of medical devices and products. The operator of medical devices is thus able, with the help of the certificate, to examine in each case whether the contractor is able to properly reprocess the medical devices submitted by the operator for reprocessing.

Legal permissibility of reprocessing single-use products pursuant to medical device law

Neither the MPG nor the ordinances enacted on the basis thereof expressly prohibit the reprocessing of single-use products. Nevertheless, the reprocessing of single-use products is disputed in the literature. This is a result of the structure of the law: pursuant to § 2 para. 1 MPBetreibV, medical devices may only be constructed, operated, used and maintained in accordance with their specifications.

The central issue in this context is whether the manufacturer’s designation as “single-use medical device” belongs to the specification or whether this is merely a restriction on the use, or a definition of a term on the part of the manufacturer.

According to one view represented in the literature, the “single-use” designation is part of the specification, since the specification does not depend only on the relevant characteristics in the medical device definition set forth in § 3 No. 1 MPG. Instead, the manufacturer would have to define additional purposes, e.g. with regard to the classification of the medical device. This view would correspond with an interpretation in line with the directive, taking into account the safety concept on which medical device law is based [3]. Were one to follow this understanding, the reprocessing of single-use products would be contrary to their purpose, and, thus, prohibited.

According to the opposing view, however, only the characteristics of a medical device specified in § 3 No. 1 MPG belong to the specifications. This would result from the definition of specifications in § 3 No. 10 MPG, which refers to the use of the product and therefore constitutes a reference exclusively to the definitions in § 3 No. 1 MPG. It is argued that with the specifications the manufacturer could only pursue goals that are designated in the definition of medical devices contained in § 3 No. 1 MPG. All further declarations are solely for the purpose of labelling ([4], [5] § 9, margin note 56).

The latter opinion should be confirmed, since the express emphasis of the intended use in the definition set forth in § 3 No. 10 MPG constitutes a pretty clear reference to the statements in the medical device definition contained in § 3 No. 1 MPG. This does not, however, include the designation “single-use product”. The safety concept of medical device law does not demand the prohibition of reprocessing of single-use products either. What is import-

ant is ensuring an appropriately high standard of quality when reprocessing, which is secured by way of the provisions of the MPBetreibV.

Ultimately the purpose of the norm, which can be derived from the legislative intent and historic interpretation, supports the permissibility of reprocessing single-use products.

The proposed resolution of the Health Committee on the 2nd Act to Amend the MPG states that the amendment shall serve to remove the legal uncertainties in the area of the reprocessing of single-use products. It states that, in the interests of consumer protection, the Federal Ministry for Health is called upon to introduce appropriate supervision of the reprocessing of single-use products [6]. Thus, the legislator is obviously proceeding on the basis that the reprocessing of single-use products is permissible, and wanted to ensure in the course of the 2nd Act to Amend the MPG that this reprocessing attains a high qualitative standard by way of appropriate supervision.

The Federal government's answer to a parliamentary question regarding the reprocessing of single-use products leads to the same outcome. According to the unequivocal answer, the reprocessing of single-use products is not prohibited. The reprocessing requirements do not differentiate between single-use and multi-use products [7].

So, the reprocessing of single-use products is legally permissible. Citing the legislative purpose, the higher courts seconded this outcome in a decision [8].

Medical device law from the point of view of liability law

As explained under point 6, the reprocessing of medical devices that are intended to be applied semi-sterile or sterile is, although it entails more stringent requirements, permissible under European and German Federal Law. However, this legislative system of values does not release the manufacturers, nor the professional operators of medical devices, from their liability under liability law for damage resulting from the use of incorrectly processed medical devices.

The civil and criminal law responsibility of a manufacturer of medical devices, or that of his authorised agents in the course of the *first* placing on the market of a medical device for faults in the construction, the manufacture and the instructions, as well as for product supervision measures that were disregarded, was expressly clarified with the entry into force of the 2nd Act to Amend the MPG on January 1, 2002 through § 6 para. 4 together with § 5 MPG: pursuant to this, the operators of medical devices are obligated to monitor compliance and correct implementation of the provisions of the MPG and the MPBetreibV by way of organisational and technical measures.

Pursuant to § 4 para. 2 sentence 1 MPBetreibV, the reprocessing of medical devices intended to be applied

semi-sterile or sterile is to be carried out taking into account the manufacturer's specifications using suitable procedures such that the success of this procedure can be verifiably ensured and the safety and health of patients, users and third parties is not put at risk (in distinction the reprocessing of medical devices that are not applied sterile usually amounts to nothing more than the measures to maintain the normal condition (servicing), i.e. simple cleaning). According to a decision of the Administrative Court Arnsberg it is therefore not sufficient if a clinic assumes that the medical devices treated in a steam steriliser are sterile, without there being a validated procedure [9].

In order to avoid any claim against the operator under liability law, the medical devices must be reprocessed in accordance with a validated and documented procedure. Only through the validation of the reprocessing procedure are the correct parameters defined, which are necessary in order to prove that the process in question was carried out in a form that guarantees effective reprocessing ([10] chapter II 3, § 4, MPBetreibV, Rn. 3).

The subject of a validation procedure must, therefore, refer to a documented procedure for the performance, recording and interpretation of the results. This is the only way that proof can be provided that products of consistently equal quality can be achieved in a reprocessing procedure [9].

The success of the proper reprocessing process is linked to a decisive degree with the knowledge of the condition of a medical device. It is above all the manufacturers who have well-founded expert knowledge of this. On grounds of patient-protection and for liability law protection, the operators should therefore request details of the appropriate validated reprocessing procedures from the manufacturers.

When a claim is made against an operator of medical devices under liability law, § 4 para. 2 sentence 3 MPBetreibV plays a central role. As explained under clause 2b, it is assumed – such assumption being refutable – that an operator or an external processor has carried out the reprocessing correctly if the reprocessing procedure complies with the Joint RKI and BfArM Recommendation.

Complying with the recommendation does not constitute a direct statutory obligation, i.e. failure to comply with it does not lead to any direct punishment of the operator. However, in the event that a claim is made under liability law, failure to comply with the recommendation can lead to an alleviation of the burden of proof on the claimant's side. The allocation of the burden of proof in the patient/operator relationship basically follows the general rules, pursuant to which the claimant carries the burden of proof for all conditions establishing his claim.

From the point of view of the law of evidence, this initially results in a comfortable position for the operator of medical devices. If, however, the aforementioned recommendations are not observed when reprocessing, then in the event of an incident the onus of presentation and

the burden of proof of proper reprocessing would be incumbent upon the operator of the medical device.

The reprocessing of medical devices belonging to the highest risk category (critical C), or of medical devices for which the manufacturer has restricted re-use (single-use products), constitute a special case. As explained above, the reprocessing of the aforementioned articles is not directly or indirectly prohibited at any point in the MPG or the MPBetreibV. On the contrary – the Federal government follows the strategy that it is possible to safely reprocess these medical devices [11].

With regard to the reprocessing too, the quality management system set up by the reprocessor must have been certified by a body accredited by the competent authority. In the case of single-use products, for which, accordingly, the manufacturer has not provided a validated procedure, it is of the utmost importance for ensuring safety that the reprocessor is able to understand the function and condition of the medical device to be reprocessed.

Only well-founded expert knowledge with regard to the material characteristics and the technical construction of a product ensure that an adequate validated reprocessing procedure can be developed, implemented and certified ([10] chapter II 3, § 4 MPBetreibV, margin note 4). If the operator outsources the task of reprocessing and has it carried out by an external third party, the selection of the reprocessor is placed in his responsibility. From the point of view of an operator of medical devices, it is therefore essential that a validated and verified procedure be provided when outsourcing the reprocessing.

In this connection, the certification of the processing company constitutes a milestone in the course of liability law risk management, because this enables the operator to ensure that the external reprocessor carries out the reprocessing properly and professionally.

Conclusion

When deciding whether to reprocess medical devices for the purpose of re-use, the benefits and risks must be carefully weighed up against each other in the interests of the efficient development of our healthcare system. According to the legislator's intention, when discussing how to finance the services required pursuant to social security law, in addition to many economic issues, sustainability must also be taken into account, i.e. in addition to economic factors, environmental aspects are increasing in importance in the course of the selection of a medical device. Here, it is the case that reprocessing, regardless of whether the medical device is declared for single use or for repeated use, appears even more worthwhile the greater the input of material and resources required in the manufacture of the medical device in question [12].

From the legal point of view, however, this discretion in the selection is, pursuant to these parameters, limited by an incontrovertible liability law factor: patient protec-

tion. Consequently, with regard to the reprocessing of single-use products in particular, it must be examined for each individual product with the greatest degree of care whether the material characteristics and the construction of the medical device allow it to be reprocessed, without this posing a risk to life or limb of the patient.

References

1. Böckmann RD, Frankenberger H, Will HG. Durchführungshilfen zum Medizinproduktegesetz. 2006.
2. RKI-Kommission für Krankenhaushygiene und Infektionsprävention. Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukte. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2001;44:1115-26.
3. Haindl H, Helle J. Die Unzulässigkeit der Wiederverwendung von Einmal-Medizinprodukten. Medizinrecht. 2001;20(8):411-8.
4. Schneider A. Description of the difference in opinion in Böckmann. Medizinrecht. 1999;19:459.
5. Anhalt E, Dieners P. Handbuch des Medizinprodukterechts. 2003.
6. Bundestag Drucksache 2001;14/7331:46.
7. Bundestag Drucksache 2002;14/8750:110.
8. OLG Koblenz. Urteil vom 30.8.2005. GRUR-RR. 2006:141.
9. VG Arnsberg. 19.11.2004 (3 L 1444/04).
10. Hill RRA, Schmitt JM. Medizinprodukterecht (WiKo). 2005.
11. Reischl W. Medizinprodukterecht im Überblick. Rechtsdep Gesundheitswes. 2006;6:180-5.
12. Kramer A, Exner M, Schneider A, Martiny H, Zastrow K-D, Christiansen B, Loczenski B, Popp W, Simon A, Wolff M, Soltau U. Ethische, hygienische und juristische Gesichtspunkte der Aufbereitung von Medizinprodukten (Gemeinsame Stellungnahme des Vorstands der DGKH und des ZLG). Hyg Med. 2006;10:466-8.

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