Verbund für Angewandte Hygiene e.V.
Desinfektionsmittel-Kommission

Quality criteria, efficacy tests and legal requirements for marketing of disinfectants for reprocessing of medical devices

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A. Introduction

In recent years, there have been many regulatory changes with regard to the classification and approval or marketability (products that are allowed to be marketed) of disinfectants in the healthcare sector. In the area of disinfectants classified as medical devices, Regulation (EU) No. 2017/745 (Medical Devices Regulation, MDR) has been applied directly and uniformly in the European Union (EU)[1] since 26 May 2021.[2] Due to the Corona pandemic, the start of application, originally scheduled for 2020, had been postponed by one year.[3] This article contains an overview of the classification of disinfectants into different product categories in Germany and Europe and presents in particular the requirements of medical device law since the MDR came into force.

B. Regulatory classification of disinfectants

In Germany, disinfectants for use in healthcare can be assigned to three different product categories:

1. Hand disinfectants have been classified as biocidal products since 2016; hand disinfectants approved as pharmaceutical drugs are grandfathered,
2. disinfectants for reprocessing of medical devices (e.g. instrument disinfectants[4]) are medical devices,
3. surface disinfectants are biocidal products.

So-called *disinfectant cleaners* are also available on the market. The database of reported biocidal products of the German Federal Institute for Occupational Safety and Health (BAuA) alone leads to 334 hits under the keyword "disinfectant cleaner". However, the term disinfectant cleaner does not exist in either medical device law or biocidal product law. Annex V of Regulation (EU) No. 528/2012 explicitly states the following:

"Main group 1: Disinfectants.
These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products."

Disinfectant cleaners and products for disinfecting cleaning are thus regulated as biocidal products under the aspect of the main mode of action: disinfection. They must also always have a safe disinfection effect for use in the one-step disinfecting cleaning of contact surfaces in healthcare facilities.

C. Regulatory requirements for biocidal products

For biocidal products, the regulations of Regulation (EU) No. 528/2012 on biocidal products and the German chemicals legislation must be observed.

According to the requirements of Regulation (EU) No. 528/2012, active substances for biocidal products must be approved. Based on this, the specific biocidal products must be authorized. Temporary transitional provisions apply to certain existing products.

1 As well as in the other EEA (European Economic Area) states Norway, Iceland and Liechtenstein; but not in Switzerland and – with the exception of Northern Ireland – not in the United Kingdom.
2 Regulation (EU) 2017/745 on medical devices, OJ L 117, 05 May 2017, p. 1.
3 Regulation (EU) 2020/561 amending Regulation (EU) 2017/745 on medical devices as regards the date of application of certain of its provisions, OJ L 130, 24 April 2020, p. 18.
4 Medical devices also include products for disinfecting surfaces of certain medical devices that cannot be immersed by applying a product with or without mechanical action, e.g., wiping, rubbing, circulating, rinsing, spraying, fogging.

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I. Approval of active substances

By Delegated Regulation (EU) No. 1062/2014, the European Commission has identified a list of active substances that should be assessed for possible approval for use in biocidal products or inclusion in Annex I to Regulation (EU) No. 528/2012.

For example, this list still includes the active ingredient ethanol for product types PT 1 (human hygiene), PT 2 (disinfectants not intended for direct application to humans or animals) and PT 4 (products for disinfection in the food and feed sector). The evaluation for the active ingredient ethanol is far behind schedule. The active substance ethanol is a candidate for active substance substitution according to Article 10 of Regulation (EU) No. 528/2012 in PT 1, 2 and 4. In the meantime, ethanol should be classified as carcinogenic, mutagenic and toxic to reproduction in the sense of Regulation (EC) No. 1272/2008 (CLP Regulation).[5] Such an active substance could only be approved for an initial period not exceeding five years[6]. The evaluation by the Biocidal Products Committee established at the European Chemicals Agency (ECHA, Article 3(1) letter x) of Regulation (EU) No. 528/2012) is pending.

Propan-2-ol has been approved by means of Implementing Regulation (EU) 2015/407 as an active substance for use in biocidal products of product types 1, 2 and 4. There are currently 6 biocidal products approved in Germany for hand disinfection with this active ingredient. In the EU, 13 biocidal products of PT 1, 70 biocidal products of PT 2 and 38 biocidal products of PT 4 are approved with the active ingredient propan-2-ol.[7]

Propan-1-ol was approved as an active substance for use in biocidal products of the product types 1, 2 and 4 by means of Implementing Regulation (EU) 2017/2001. In the EU, 3 biocidal products of PT 1, 4 biocidal products of PT 2 and 4 biocidal products of PT 4 are approved with the active substance propan-1-ol. These approvals were all granted in Germany.[8]

On 8 July 2022, the European Commission granted a Union authorization for the biocidal product family "L+R Propanol PT1 Family".[9] This biocidal product family contains the active substances 45% propan-2-ol, 30% propan-1-ol and the non-active substance tetradecanol 0 to 0.95%.

Based on an implementing decision of the European Commission applicable throughout the EU and the EEA[10], products containing 2-propanol and intended for hand disinfection – including surgical hand disinfection – have been considered biocidal products since 2016.

There is no such decision for hand disinfectants containing 1-propanol. However, the justification of the Implementing Decision (EU) 2016/904 would be transferable to this active substance. Therefore, a classification as a biocidal product must also be assumed in this respect.

There is also no classification decision for hand disinfectants containing ethanol. Ethanol – in contrast to 2-propanol and 1-propanol – has not yet been approved as an active substance for disinfectants. However, it is also true for ethanol that the reasoning of the Implementing Decision (EU) 2016/904 would also be applicable to this active substance.

Sometimes active ingredients are also not approved. An example of this is polyhexamethylene biguanide (PHMB) for PT 1, 6 and 9.[11] As a rule, products containing these non-approved active ingredients are subject to a sell-off period of one year.

Examples of approved active ingredients for biocides:

- Propan-1-ol (for PT 1, 2, 4)
- Propan-2-ol (for PT 1, 2, 4)

Examples of unapproved active ingredients for biocides:

- Polyhexamethylene biguanide (PHMB) (for PT 1, 6, 9)
- Glutaral (for PT 1, 13)
- Triclosan (for PT 1, 2, 7, 9)

Examples of active ingredients for which a decision has not yet been made:

- Ethanol (für PT 1, 2, 4)

II. Authorization of biocidal products

With the exception of biocidal products that are allowed to be marketed under transitional provisions, all biocidal products require an authorization to be allowed to be marketed.

In the field of biocidal products, there is basically the national authorization, the mutual recognition procedure for national authorizations (when a product is marketed in several Member States), and the Union authorization.

For certain products, that do not contain substances of concern, for example, there is a simplified procedure.

There is also an option to apply for authorization of a biocidal product that is either identical to an already authorized biocidal product or identical to a biocidal product for which an application for authorization is pending.

For the evaluation of efficacy in authorization procedures, ECHA has issued guidelines containing general requirements and requirements for individual product types.[12] These guidelines thus also contain the requirements for the efficacy of disinfectants.

III. Transitional provisions

Until a decision has been made on whether or not to approve the active substances, biocidal products may be placed on the market, made available on the market and used without approval. *Registration* with the BAuA is sufficient for this. The BAuA issues a registration number (e.g. **N-12345**), die auf dem Etikett des Produktes mitgeteilt werden muss. This registration number is not to be confused with an approval number (e.g. **EU-1234567-0000** or **DE-1234567-01-0001-01**).

5 *Kramer et al.*, Antimicrobial Resistance & Infection Control (2022) 11:93, DOI https://doi.org/10.1186/s13756-022-01134-7, accessed 23 September 2022.
6 Otherwise, approval will be granted for an initial period not to exceed ten years.
7 https://echa.europa.eu/information-on-chemicals, as of 05 October 2022.
8 https://echa.europa.eu/information-on-chemicals, as of 05 October 2022.
9 Implementing Regulation (EU) 2022/1186 granting a Union authorisation for the biocidal product family „L+R Propanol PT1 Family", OJ L 184, 11 July 2022, p. 41.
10 Implementing Decision (EU) 2016/904 of 08.06.2016 pursuant to Article 3(3) of Regulation (EU) No. 528/2012 on 2-propanol-containing products for hand disinfection, OJ L 152, 09 June 2016, p. 45.
11 Implementing Decision (EU) 2016/109 of 27.01.2016 concerning the non-authorization of PHMB (1600;1.8) as an existing active substance for use in biocidal products of product types 1, 6 and 9, OJ L 21, 28 January 2016, p. 84.
12 Example: Guidance on the Biocidal Products Regulation Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 4.1, February 2022.

If, after approval of an active substance or the last active substance contained in the biocidal product, no application for approval or parallel recognition has been submitted, the biocidal product may no longer be made available on the market 180 days after the date of approval of the active substance or substances. Stocks may continue to be used for up to 365 days after the date of approval of the active substance(s). The date of approval of the active ingredient is usually approximately 18 months after the decision. This period is intended to allow affected parties to make the necessary preparations to comply with the new requirements.

Products containing non-approved active ingredients are generally subject to a one-year sell-off period. After this period, these products are no longer allowed to be marketed. 18 months after publication of the implementing decision on the non-approval, a product containing the active substance may no longer be used, unless otherwise specified in the implementing decision, see: Section 28 (8) sentence 2 no. 1 of the German Chemicals Act. The term use includes all actions carried out with a biocidal product, including storage, handling, mixing and application, except for actions that take place to export the biocidal product or treated article[13] from the Union, see: Article 3(1) letter k) of Regulation (EU) No. 528/2012. Of course, no authorization can be applied for these products either.

D. Regulatory requirements for medical devices

I. Regulation (EU) No. 2017/745 (MDR)

Since 26 May 2021, the MDR applies to medical devices in the EU/EEA. Article 2 No. 1 MDR contains the definition of the term *medical device*, which essentially corresponds to the known definition in Article 1(2) letter a) of Directive 93/42/EEC or Section 3 No. 1 of the repealed German Medical Devices Act (MPG).

What is new, however, is that this definition also includes products that are specifically intended for the cleaning, disinfection or sterilization of medical devices and accessories.[14] Thus, including but not limited to, the following products are medical devices and not only accessories:

- washer-disinfectors,
- sterilizers,
- process chemicals for washer-disinfectors (cleaners, disinfectants),
- other disinfectants for medical devices (manual methods of disinfection).

Products that are intended solely for surface disinfection and are not intended for the disinfection of medical devices, are not medical devices. No CE marking must be applied to these products, and they must not be marketed as medical devices. Dual-use products are shown below (see: D. III.).

The choice of the applicable conformity assessment procedure is based on Article 52 MDR and Annex VIII of the MDR (classification rules).

1. Classification of disinfectants for medical devices

Rule 16 of Annex VIII of the MDR contains the following classification rules for cleaning and disinfecting products:

All products specifically intended to disinfect, clean, rinse or, where appropriate, hydrate contact lenses are classified as Class IIb.

Disinfectant solutions and washer-disinfectors specifically intended for disinfection of invasive devices as the end point of reprocessing are in Class IIb.

According to Article 2 No. 6 MDR, an *invasive device* is a device that, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. Examples are endoscopes, tubes, catheters, and surgical instruments.

All other devices intended specifically for disinfecting or sterilizing medical devices are classified as class IIa.

However, Rule 16 does not apply to products intended for cleaning products other than contact lenses by physical action alone.

Interpretative guidance on classification can be found in MDCG Guideline MDCG 2021-24, Guidance on classification of medical devices,[15] as of October 2021.

The MDCG is the Medical Device Coordination Group according to Article 103(1) MDR. It consists of members appointed by the Member States on the basis of their expertise and experience in the field of medical devices and in vitro diagnostics (IVD). These members represent the competent authorities of the Member States. The tasks of the MDCG result from Article 105 and partly from Article 106 MDR. Tasks include contributing to the development of guidance for the effective and harmonized implementation of the MDR, and contributing to the development of standards, common specifications and scientific guidance, including product-specific guidance. The MDCG has already issued more than 100 guidelines.[16] According to the MDCG's work plan, another 31 guidance documents are expected to be published in 2022.

The MDCG guidelines are not legally binding. However, they are suitable as an interpretation guide, especially since the members of the MDCG are delegated by the competent authorities of the Member States.

Disinfectants for medical devices thus fall under classes IIa or IIb.

2. Conformity assessment procedure for disinfectants for medical devices

This means that the involvement of a notified body in the conformity assessment procedure is mandatory. The user can recognize this by the four-digit identification number of the notified body, which must be attached to the CE marking.

Manufacturers of class IIb devices are subject to a conformity assessment according to Article 52(4) MDR in accordance with Annex IX Chapters I and III, as well as an assessment of the technical documentation – according to Section 4 of the said Annex – of at least one representative device per *generic device group*. Alternatively, manufacturers may opt for a conformity assessment according to Annex X in combination with a conformity assessment according to Annex XI.

13 Treated article means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products, see: Article 3(1) letter l) of Regulation (EU) No. 528/2012.

14 As well as non-medical devices listed in Annex XVI of the MDR that fall within the scope of the MDR, e.g. contact lenses without a medical purpose for changing eye color.

15 Guideline for the classification of medical devices.

16 https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en, accessed on 20 September 2022.

According to Article 2 No. 7 MDR, the *generic device group* is a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

According to MDCG-Guideline MDCG 2019-13, Guidance on sampling of MDR Class IIa/Class IIb and IVDR Class B/Class C devices for the assessment of the technical documentation,[17] December 2019, this is the 4th level of the European Medical Device Nomenclature (EMDN).[18] Alcohol-based disinfectants for medical devices only extend to the 3rd level in the EMDN.[19] Example of 4th level is glutaraldehyde for disinfection of medical devices (D010101).

Manufacturers of class IIa devices are subject to a conformity assessment according to Annex IX Chapters I and III and a technical documentation assessment – according to Section 4 of that Annex – of at least one representative device of each device category, according to Article 52(6) MDR. Alternatively, manufacturers may choose to prepare the technical documentation referred to in Annexes II and III, in combination with a conformity assessment in accordance with Section 10 or Section 18 of Annex XI, after which the technical documentation assessment shall also be carried out for at least one representative product of each *product category*.

The *product category* is according to MDCG-Guideline MDCG 2019-13, the MDA or the MDN code according to Implementing Regulation (EU) 2017/2185.[20] The MDN 1211 code designates non-active non-implantable products for disinfection, cleaning, and irrigation.

For disinfectants, the manufacturer's quality management system is assessed when the conformity assessment according to Annex IX is chosen. The audit of the notified body also includes an assessment of the technical documentation for representatively selected devices according to Section 4 of Annex IX of the MDR. In selecting representative samples, the notified body shall take into account MDCG guidance and, in particular, technological novelty, similarities in design, technology, manufacturing and sterilization processes, intended purpose and the results of any relevant previous assessments, e. g. with regard to physical, chemical, biological or clinical properties, carried out in accordance with the MDR.

3. Compliance with the general safety and performance requirements

According to Article 5(2) MDR, each product must comply with the general safety and performance requirements set out in Annex I of the MDR.

According to Article 10(9) MDR, the manufacturer's quality management system shall mandatorily include the identification of the applicable general safety and performance requirements and the identification of ways to comply with these requirements.

Confirmation of compliance with the relevant general safety and performance requirements is based on clinical data, with justification, if necessary, based solely on the results of non-clinical test methods, see: Article 61(1) MDR and Article 61(10) MDR.

According to the general safety and performance requirements of Annex I of the MDR, devices must achieve the performance intended by their manufacturer and be designed and manufactured to be fit for their intended purpose under normal conditions of use. Devices must be safe and effective and must not endanger patients, users or third parties. Any risks must be acceptable in relation to the benefit to the patient and compatible with a high level of health protection and safety. The yardstick for this is the generally recognized state of the art.

4. Harmonized standards

In order to simplify and harmonize these requirements, the EU legislator has established the concept of harmonized standards for many years.

Products that comply with harmonized standards or the relevant parts of these standards are presumed to conform to the requirements of the MDR in accordance with Article 8(1) MDR. The references of the harmonized standard must be published in the Official Journal of the EU.

Provisions identical in content regarding the presumption of conformity with the essential requirements in the case of conformity with harmonized standards were contained in the provisions of Section 8(1) of the MPG and Article 5(1) of Directive 93/42/EEC, which have expired.

Since conformity with the MDR is only *presumed*, it must be assumed that there is no obligation to comply with harmonized standards.[21]

This follows from the wording and the systematics of the relevant provisions.

It is true that the 22nd recital of the MDR indicates that, in view of the important role played by standardization in the field of medical devices, manufacturers *should* be able to demonstrate conformity with the essential safety, performance and other regulatory requirements laid down in the MDR, for example on quality and risk management, by complying with the harmonized standards.

However, this does not yet constitute an obligation to comply with harmonized standards.

First, the recitals are not legally binding. They cannot be used to derogate from the provisions of the act in question, nor to interpret those provisions in a sense that is manifestly contrary to their wording.[22]

Only the wording of the MDR regulations is therefore binding.

The MDR provisions do not provide for the mandatory application of harmonized standards. Article 8(1) of the MDR merely contains a presumption of conformity with the MDR in the case of conformity of devices with harmonized standards. Conversely, the application of harmonized standards is not mandatory in the conformity assessment procedure.

There is a certain difference to the common specifications according to Article 9 MDR.

17 Guideline for sampling MDR Class IIa/Class IIb and IVDR Class B/Class C devices for technical documentation evaluation.
18 European nomenclature for medical devices.
19 D0701: Ethanol for disinfection of medical devices; D0702: Isopropanol for disinfection of medical devices.
20 Implementing Regulation (EU) 2017/2185 on the list of codes and their corresponding product types for determining the scope of designation of a notified body, OJ L 309, 24 November 2017, p. 7.
21 On the voluntary nature of the use of harmonized standards under Directive 93/42/EEC: Benad/Graf/Lau/Pleiss, Praxis Medizinprodukterecht, as of September 2022, ch. 04008, 4.1.
22 ECJ, Judgment of 19 June 2014 – C-345/13 –, juris, with further references.

According to Article 2 No. 71 MDR, common specifications are a set of technical and/or clinical requirements, other than a standard, compliance with which makes it possible to meet the legal obligations applicable to a device, process or system. To date, the European Commission has only issued common specifications for the reprocessing of single-use devices.[23]

Article 9(3) MDR stipulates that manufacturers must comply with the common specifications unless they adequately demonstrate that the solutions they have chosen ensure a level of safety and performance at least equivalent to these. There is no such provision in the case of harmonized standards. Moreover, manufacturers may also deviate from common specifications in the case of comparable solutions. If deviations are permissible in the case of common specifications, this must apply a fortiori when harmonized standards, for which no binding is prescribed, are at issue.

Secondly, the 22nd recital only uses the word *should* – with less binding force – and not *shall* or *must*.

Finally, the voluntary nature of the application of harmonized standards – by way of systematic interpretation – also results from the MDR's annexes on conformity assessment.

Thus, in accordance with Section 3(g) of Annex X to the MDR, the notified body shall, inter alia, carry out assessments and inspections or laboratory tests to determine whether the relevant harmonized standards have actually been applied, *insofar* the manufacturer has chosen to apply those standards.

A deviation from harmonized standards is therefore permissible, as the use of the wording *insofar* makes clear. In this case, however, other proof of the product's conformity with the requirements of the MDR is required.[24]

Since such other proof will usually be a very complex matter, it can be assumed in most cases that manufacturers will comply with harmonized standards.

5. Harmonized standards for disinfectants

For disinfectants, there are currently no harmonized standards within the scope of MDR. Within the scope of Directive 93/42/EEC, the following standards were harmonized in the area of disinfectants:

- EN 13624:2003 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of the fungicidal activity of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2, step 1),
- EN 13727:2012 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1),
- EN 14348:2005 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test methods and requirements (phase 2, step 1),
- EN 14561:2006 – Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2),
- EN 14562:2006 – Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2),
- EN 14563:2008 – Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area – Test method and requirements (phase 2, step 2).

The different parts of EN ISO 15883 concern washer-disinfectors and are at best relevant with regard to the combinability of washer-disinfectors and process chemicals.

It can be assumed that the above mentioned standards will also become harmonized standards within the scope of MDR.

However, so far there is a standardization mandate from the European Commission only with regard to EN 14885:2018 (Chemical disinfectants and antiseptics – Application of European standards for chemical disinfectants and antiseptics).

EN 14885[25] specifies the laboratory tests to be used when testing the effect of chemical disinfectants and antiseptics. In doing so, the standard specifies the European standards to which products have to conform in order to support the claims for microbicidal[26] activity which are referred to in this standard.

In the field of instrument disinfection, DIN EN 14885:2022-10 lists EN 13624, EN 13727, EN 14348, EN 14561, EN 14562, EN 14563, EN 14476, EN 17111 and EN 17126 for applicable standard test methods to substantiate product claims.[27]

The test standards used in the conformity assessment procedure for the medical device are not specified in the EU declaration of conformity. They can either be found in the product information or must be requested from the manufacturer.

II. Transitional provisions

The MDR also contains transitional provisions. Article 120 MDR regulates the validity of certificates issued by notified bodies and transitional periods for placing on the market, putting into service and making available on the market for existing devices (conformity assessed e. g. according to Directive 93/42/EEC, also known as *legacy devices*).

Certificates issued by notified bodies in accordance with Directive 90/385/EEC or Directive 93/42/EEC remain valid in accordance with Article 120(2) MDR until the end of the validity period, but no later than 26 May 2024.[28]

Legacy devices with a certificate valid according to Article 120(2) MDR may, according to Article 120(3) MDR,

23 Implementing Regulation (EU) 2020/1207 laying down rules for the application of the MDR as regards common specifications for the reprocessing of single use devices, OJ L 273, 20 August 2020, p. 3.
24 For alternative proof of conformity: ECJ, judgment of 27.10.2016 – C-613/14 –, juris.
25 Now available as EN 14885:2022 and (German) DIN EN 14885:2022-10.
26 Also called *microbiocidal effect*.
27 Section 4.3.1 of DIN EN 14885:2022-10 (Table 1).
28 As of 26.05.2021, certificates in accordance with Directives 90/385/EEC and 93/42/EEC must no longer be issued.

be placed on the market or put into service until 26 May 2024 at the latest, provided that they continue to comply with Directive 90/385/EEC, resp. with Directive 93/42/EEC, since 26 May 2021 and that there are no significant changes in the design and intended use.

Legacy devices that have been placed on the market since 26 May 2021, in accordance with Article 120(3) of the MDR may continue to be made available on the market or put into service until 26 May 2025, in accordance with Article 120(4) of the MDR.

Thus, as of 26 May 2024 at the latest, only disinfectants for medical devices that have undergone a conformity assessment procedure in accordance with MDR may be placed on the market.

From 26 May 2025, also in the further supply chain, only the further making available of disinfectants for medical devices on the market that have undergone a conformity assessment procedure according to MDR is permitted.

Disinfectants for medical devices that are allowed to be marketed as legacy devices had to be conformity assessed according to the regulations of Directive 93/42/EEC. These disinfectants were considered accessories to medical devices. However, the same legal regulations applied to accessories as to medical devices.

III. Dual-use products

In practice, disinfectants are also marketed that have a purpose as both a medical device disinfectant and a surface disinfectant.

Such dual use is established in administrative practice in Germany and other EU countries.

The MDR does not contain any explicit provisions on dual use. However, Article 1(3) MDR stipulates that devices with medical and non-medical intended purpose must fulfill both the requirements for devices with medical intended purpose and the requirements for devices without medical intended purpose.

Regulation (EU) No. 528/2012 does not apply to medical devices according to the provision in Article 2(2) letter b),[29] however, the second subparagraph of this provision stipulates that Regulation (EU) No. 528/2012 nevertheless also applies to biocidal products that fall within the scope of the MDR, have a purpose outside the MDR and this purpose is also not covered by the MDR.

This is precisely the case with dual use as both a disinfectant for medical devices and as a surface disinfectant.

These products must then comply with both the MDR and Regulation (EU) No. 528/2012 and be labelled in accordance with both medical device and biocidal product legislation.

A disposable disinfection wipe for wipe disinfection intended for both medical devices and surfaces must comply with both medical device and biocidal product legislation as a dual-use product. For the medical device portion, the use of transitional provisions may be considered. In terms of biocidal product legislation, the products are often still marketed under transitional legislation with simple registration.

From 26 May 2025 at the latest, conformity assessment in accordance with MDR is required under medical device law. However, the transitional regulations in the area of biocidal products apply in part for much longer.

E. EXCURSUS: Regulatory requirements for pharmaceuticals

Quality, efficacy and safety are tested as part of the pharmaceutical drug approval process.

In principle, there are three different marketing authorization procedures – similar to those for biocidal products: Union authorization with the European Medicines Agency (EMA), national authorization by national regulatory authorities, and mutual recognition of national authorizations (when a pharmaceutical drug is marketed in several Member States).

In addition to administrative data on the pharmaceutical drug, the marketing authorization application must be accompanied by the results of physical, chemical, biological or microbiological tests and the methods used to determine them (analytical testing), the results of pharmacological and toxicological tests, the results of clinical trials or other medical or dental testing, a description of the pharmacovigilance system, the risk management plan with a description of the risk management system, and a confirmation from the marketing authorization holder, resp. the applicant, that it has satisfied itself of compliance with good manufacturing practice in the manufacture of active ingredients by means of an on-site inspection. In the case of applications for marketing authorization of generic drugs, the submission of the results of preclinical and clinical trials is not required.

For pharmaceutical drugs with active substances that have been in general medical use in the EU for at least ten years, other scientific evidence may be submitted instead of the results of pre-clinical tests and clinical trials.

Some hand disinfectants are approved as pharmaceutical drugs in Germany.

These pharmaceutical drugs have grandfather status in Germany in accordance with Section 2(4) Sentence 1 of the German Pharmaceuticals Act (AMG) – despite their European classification as biocidal products. This provision stipulates that a product that is approved as a pharmaceutical drug under the AMG is considered a pharmaceutical drug. The provision is designed as an irrebuttable presumption. The provision serves the purpose of legal certainty and grandfathering.[30]

A product that is not (or no longer) covered by the definition of a pharmaceutical drug in Section 2 of the AMG, but has a marketing authorization for a pharmaceutical drug, is therefore nevertheless classified as a pharmaceutical drug. In this case, a pharmaceutical drug is fictitiously assumed. This is because the fictitious definition of a pharmaceutical drug also applies if the product later no longer meets the corresponding material criteria for assessment as a pharmaceutical drug.[31]

This fictitious pharmaceutical drug always applies only to the specific product for which a marketing authorization has been granted. The fictitious pharmaceutical drug does not apply to sub-

29 Cited are Directives 90/385/EEC and 93/42/EEC; this is now to be read as a reference to the MDR.

30 *Kügel/Müller/Hofmann,* German Pharmaceuticals Act , 3rd edition 2022, § 2, marginal no. 239; BT-Drs. 16/12256, p. 41 on the justification of the doubt rule; cf. also: *Sander,* Pharmaceuticals Law Commentary, as of December 2020, § 2 AMG, marginal no. 40.

31 *Fuhrmann/Klein/Fleischfresser,* Pharmaceuticals Law, 3rd edition 2020, § 2, marginal no. 26.

stance-matched products that do not have a marketing authorization.[32]

The fictitious pharmaceutical drug resulting from the authorization has a binding effect for all authorities. It has a binding effect on the marketing of pharmaceutical drugs and on the surveillance activities and powers of the supervisory authorities of the German Federal States. The fictitious pharmaceutical drug is therefore irrebuttable. It also applies to competitors. The binding effect lasts as long as the pharmaceutical drug is authorized.[33]

Compared to the classification as a biocidal product, the classification as a pharmaceutical drug has the advantage that there is no requirement of active substance approval for pharmaceutical drugs. In contrast to biocidal products, there is no list of active substances for pharmaceutical drugs that are to be replaced or classified as non-marketable. The discussion surrounding the approval of the active substance ethanol for disinfectants in particular shows that German healthcare facilities will continue to rely on hand disinfectants approved as pharmaceutical drugs in the future.

F. Conclusion

In Germany, disinfectants for use in healthcare can be assigned to various product categories. Hand disinfectants have been classified as biocidal products since 2016. Hand disinfectants classified as pharmaceutical drugs are grandfathered. Disinfectants for medical devices (e. g. instrument disinfectants or disinfectants for wipe or immersion disinfection of medical devices) are medical devices, surface disinfectants are biocidal products.

The MDR applies to disinfectants for medical devices since 26 May 2021. However, there are transitional provisions for legacy products. These disinfectants are generally assigned to classes IIa and IIb. Harmonized standards for the MDR are currently in the standardization process.

Medical device manufacturers are not required to comply with harmonized standards. However, since compliance with harmonized standards demonstrates conformity with the requirements of the MDR, manufacturers comply with harmonized standards in practice.

Dual-use products intended for the disinfection of medical devices and surfaces must comply with both medical device and biocidal product legislation.

Conflict of Interest:
This article was written on behalf of the Association for Applied Hygiene (VAH). In addition, the author serves as legal counsel to the pharmaceutical and medical device industries but has no conflict of interest as defined by the guidelines of the International Committee of Medical Journal Editors.

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32 *Kloesel/Cyran*, Commentary on the German Pharmaceuticals Act, as of January 2022, § 2 AMG, para. 165f.

33 *Kloesel/Cyran*, Commentary on the German Pharmaceuticals Act, as of January 2022, § 2 AMG, paras 165f and 168; *Koyuncu* in: *Deutsch/Lippert*, Commentary on the German Pharmaceuticals Act, 3rd edition 2010, § 2, marginal no. 107.