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Bilingual
雙語

Wo finden sich Informationen zur Validierungshäufigkeit von Prozessen im RDG und Dampfsterilisator?

Where to find information on the validation frequency of processes in the washer-disinfector and steam steriliser

在哪裡可以找到有關清洗消毒器和蒸氣滅菌器中流程確效頻率的信息?

Editorial社論

Dear readers of aseptica親愛的讀者們,

Summertime is the best time of the year for many, regardless of whether you spend your vacation on the balcony, in the garden or on a vacation trip. A little time away from the daily grind is good for us all. But to make sure it doesn't get too boring despite all the vacation anticipation, we are publishing our second aseptica issue 2025 just in time.對許多人來說，夏天是一年中最美好的時光，無論你是在陽台、花園裡，還是在戶外度假。暫時告別日常的紛擾，享受片刻寧靜，對我們所有人都有益。但為了避免假期過後過於沉悶，我們適時推出了《無菌》2025 年第二期。

This issue focuses on the topic of "Validation of reprocessing processes" with the two articles "Where can information be found on the validation frequency of processes in the washer-disinfector and steam sterilizer" by Ms. Nehr-Werner and Dr Weber and the article by Mr. Streller "Maintaining the validator's knowledge" through the DGSV refresher.本期重點關注"再處理流程的確效"主題，其中包括 Nehr-Werner 女士和 Weber 博士撰寫的兩篇文章"在哪裡可以找到有關清洗消毒器和蒸汽滅菌器中流程確效頻率的信息"，以及 Streller 先生撰寫的文章"通過 DGSV(Deutsche Gesellschaft für Sterilgutversorgung e.V.德國無菌供應協會) 複習保持確效者的知識"。

In his short article, Dr. Jakel explains the most important new features of the revised Medical Devices Operating Ordinance, which came into force on February 20th, 2025. What's new and what you need to consider. Jakel 博士在他的短文中闡述了修訂後的《醫療器材運作條例》（該條例於 2025 年 2 月 20 日生效）中最重要的新特點。其中介紹了哪些新內容以及您需要注意的事項。

In the "Miscellaneous" section, we cordially invite the graduates of Expert course III to send us their theses for publication in aseptica. With aseptica, we offer a platform for the publication of specialist topics from practice for practice. 在「雜項」版塊，我們誠摯邀請專家課程三的畢業生將他們的論文提交給我們，以便在《無菌》上發表。透過《無菌》，我們提供了一個平台，用於發表與實踐相關的專業主題。

Take advantage of the holiday break and expand your knowledge with the latest issue of aseptica.利用假期休息時間，閱讀最新一期的《無菌》來擴展您的知識。

I wish you a wonderful holiday season and lots of fun reading.祝您有個愉快的假期並享受閱讀的樂趣。

Stay healthy保持健康!

Iven Kruse

Interesting news有趣的新聞

Bacteria help produce paracetamol from old PET bottles細菌幫助利用舊的PET(聚脂塑料, 聚對苯二甲酸乙二酯)瓶生產乙醯氨基酚(普拿疼的主要成分)

Scottish biotechnologists at the University of Edinburgh have developed a new approach to producing the active ingredient paracetamol from recycled PET bottles. The team led by Stephen Wallace combined non-enzymatic reactions with genetically modified *Escherichia coli* (*E. coli*) bacteria in the laboratory.愛丁堡大學的蘇格蘭生物技術專家開發出一種利用回收PET瓶生產活性成分乙醯氨基酚的新方法。 Stephen Wallace領導的團隊在實驗室中將非酵素反應與基因改造大腸桿菌（*E. coli*）細菌結合。

First, the researchers chemically broke down PET into specific ester compounds. These esters were then converted non-enzymatically into p-aminobenzoic acid (PABA) in the presence of the *E. coli* bacteria. This so-called Lossen degradation does not actually occur in nature and normally takes place under conditions that are harmful to bacteria.首先，研究人員將PET化學分解成特定的酯類化合物。然後在大腸桿菌的作用下，這些酯類非酵素轉化為對氨基苯甲酸（PABA）。這種所謂的Lossen降解實際上並不在自然界中發生，通常發生在對細菌有害的條件下。

However, the researchers succeeded in designing the Lossen degradation process in such a way that the bacteria were not harmed. The *E. coli* bacteria were genetically modified so that they could produce paracetamol from the resulting PABA. Genes from the fungus *Agaricus bisporus* and the bacterium *Pseudomonas aeruginosa* helped in this process.然而，研究人員成功地設計了Lossen降解過程，使其不會對細菌造成傷害。大腸桿菌經過基因改造，使其能夠利用產生的對氨基苯甲酸（PABA）來生產乙醯氨基酚。真菌-雙孢蘑菇和細菌-綠膿桿菌的基因也參與了這個過程

By fine-tuning the conditions, the researchers achieved a 92 % conversion of the ester obtained from PET waste into paracetamol. According to the researchers, this new approach is more sustainable than the traditional production of paracetamol from fossil fuels such as petroleum. It causes virtually no CO_2 emissions. The results of the study were published in the journal Nature Chemistry [2025; DOI: 10.1038/s41557-025-01845-5].透過微調條件，研究人員將從PET廢料中提取的酯類轉化為乙醯氨基酚的轉化率達到了92%。研究人員表示，這種新方法比傳統的利用石油等化石燃料生產乙醯氨基酚的方法更具永續性，幾乎不會產生二氧化碳排放。這項研究結果發表在《自然化學》雜誌[2025：DOI：10.1038/s41557-025-01845-5]。

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1. Introduction介紹

The revised Medical Devices Operator Ordinance (MPBetreibV) [1] came into force on 20 February 2025. At the same time, the First Ordinance amending the Medical Devices Operator Ordinance [2] came into force. The revised MPBetreibV must be read in the version of the first amending ordinance. Otherwise, the legal user would be assuming an outdated legal situation.修訂後的《醫療器材運作者條例》（MPBetreibV:是德國國家條例，詳細規定了德國境內醫療器材和體外診斷醫療器材的操作、維護和使用要求。）[1]於2025年2月20日生效。同時，修訂《醫療器材運作者條例》的第一條例[2]也生效。修訂後的MPBetreibV《醫療器材運作者條例》必須以第一修訂條例的版本解讀。否則，法律使用者將被視為處於過時的法律狀態。

The draft [3] submitted by the Federal Ministry of Health (BMG) in May 2024 was adopted by the Federal Council in early July 2024 with numerous amendments [4]. Accordingly, the BMG could have promulgated the new version of the MPBetreibV with the Bundesrat's amendments in the Federal Law Gazette or waived the new regulation. Another option would not have been feasible for the time being due to the need for the approval of the Bundesrat. Following negotiations between the federal and state governments, an agreement was then reached at the end of 2024 regarding the reprocessing of single-use devices that these regulations should remain at the level of the MPBetreibV prior to the new version [5]. This resulted in the simultaneous entry into force of the new version of the MPBetreibV and its first amendment – after renewed referral to the Bundesrat [6].聯邦衛生部 (BMG) 於 2024 年 5 月提交的草案 [3] 於 2024 年 7 月初由聯邦委員會通過，並包含多項修訂 [4]。因此，BMG 可以選擇在《聯邦法律公報》上公佈包含聯邦參議院修訂內容的新版 MPBetreibV《醫療器材運作者條例》，或放棄新法規。由於需要聯邦參議院批准，其他選擇目前尚不可行。經過聯邦政府和州政府的談判，最終於 2024 年底就一次性設備再處理達成協議，這些法規應保留新版 MPBetreibV《醫療器材運作者條例》之前的水平 [5]。這導致新版 MPBetreibV《醫療器材運作者條例》及其第一修正案在再次提交聯邦參議院後同時生效 [6]。

2. Overview of changes變更概述

In addition to the changes to terms, the updated MPBetreibV mainly contains innovations and clarifications in the following areas:除了條款的修改外，更新後的MPBetreibV《醫療器材運作者條例》主要在以下幾個方面進行了創新和澄清：

- Operator obligations for products with which patients are treated and which are used by them (3 MPBetreibV)運作者對患者接受治療並所使用的產品的義務（§ 3 MPBetreibV），
- general (§4 MPBetreibV) and special requirements一般要求（§ 4 MPBetreibV）和特殊要求(5 MPBetreibV),
- Representative for medical device safety醫療器材安全代表 (§6 MPBetreibV),
- Maintenance of products 產品維護(§7 MPBetreibV),
- Reprocessing of reusable devices可重複使用設備的再處理 (§8 MPBetreibV) and reprocessing of single-use devices和一次性設備的再處理 (§9 MPBe-treibV),
- Operation and use of selected active products 所選活性產品的操作和使用(§ 11 MPBetreibV),
- Safety inspections 安全檢查(STK, § 12 MPBetreibV),
- Medical device logbook 醫療設備日誌(§ 13 MPBetreibV) and inventory庫存 (§ 14 MPBetreibV),
- Metrological controls計量控制 (MTK, § 15 MPBetreibV),
- Special obligations for certain software 某些軟體的特殊義務(§ 17 MPBetreibV) and
- Administrative offenses 行政違法行為(§ 19 MPBetreibV).

The following section deals with new terms and the most important changes to software, changes to maintenance, the reprocessing of medical devices, including single-use devices, and the return of the obligation to affix labels in accordance with .以下部分涉及新術語和最重要的軟體變更、維護變更、醫療器材（包括一次性設備）的再處理，以及根據STK(定期安全測試) 和 MTK(計量檢測)貼標籤之義務的恢復。

3. New and modified terms in the MPBetreibV
MPBetreibV《醫療器材運作者條例》中的新增與修改條款

With the updated MPBetreibV, some terms have been changed or adapted to Regulation (EU) 2017/745 (MDR), Regulation (EU) 2017/746 (Regulation on in vitro diagnostic medical devices, IVDR) and the Medical Devices Implementation Act (MPDG)隨著 MPBetreibV《醫療器材運作者條例》的更新，一些術語已更改或適應法規 (EU) 2017/745（MDR）、法規 (EU) 2017/746（體外診斷醫療器材法規，IVDR）和醫療器材實施法案（MPDG）。

Instead of the term *medical device*, the term *product* is now used – as in the MDR and MPDG.現在不再使用「醫療器材」一詞，而是使用「產品」一詞，就像在 MDR 和 MPDG 中一樣。 The MDR designates as *products*: Medical devices, their accessories and products according to Annex XVI of the MDR, Art. 1 para. 4 MDR. The definition of the term *products* in Section 3 No. 1 MPDG, which is relevant for the MPBetreibV, includes in-vitro diagnostics (IVD) and their accessories and defines the generic term *products*: Medical devices, their accessories and the devices listed in Annex XVI of the MDR and falling within the scope of the MDR, as well as IVDs and their accessories. This means that the term *products* is now also used more consistently in German medical device law. However, the term *Medical Devices Operator Ordinance* remains. The *medical device register* and the *medical device safety officer* have not been renamed either.MDR 將產品指定為：依據 MDR 附件 XVI 第 1 條第 4 款的醫療器材、其配件和產品。與 MPBetreibV 《醫療器材運作者條例》相關的 MPDG 第 3 節第 1 號中術語「產品」的定義包括體外診斷 (IVD) 及其配件，並定義了通用術語「產品」：醫療器械、其配件和 MDR 附件 XVI 中列出的屬於 MDR 範圍的器械，以及 IVD 及其配件。這意味著「產品」一詞現在在德國醫療器材法中也得到更一致的使用。但是，「醫療器材運作者條例」一詞仍然保留。醫療器材註冊簿和醫療器材安全官也沒有更名。

In addition, the MPBetreibV now uses the term "*Anwender*" instead of "*Benutzer*" which in English both means user. According to § 2 (3) MPBetreibV, a "*Benut-zer*" (user) is anyone who uses a product on a patient within the scope of the MPBetreibV. 此外，MPBetreibV 現在使用"Anwender"一詞，而不是"Benutzer"，這兩個詞在英語中均指**使用者**。根據 MPBetreibV《醫療器材運作者條例》第 2 條第 (3) 款，「Benutzer」（使用者）是指在 MPBetreibV《醫療器材運作者條例》適用範圍內對患者使用產品的任何人。

The term “Anwender” is now only used in the MDR and, with Art. 2 No. 37 MDR, refers to any healthcare professional or layperson who uses a medical device. The BMG wanted to keep laypersons out of the scope of the MPBetreibV and therefore changed the term.「Anwender」（使用者）一詞目前僅在MDR中使用，根據MDR第2條第37款，該術語指使用醫療器材的任何醫療專業人員或非專業人士。 BMG希望將非專業人士排除在MPBetreibV《醫療器材運作者條例》的適用範圍之外，因此修改了該術語。

The term “*provider*” is new. According to §2 (5) MPBetreibV, a *provider* is anyone who has a legal or contractual obligation to provide products to the patient. This can be health insurance funds, accident insurance funds and long-term care insurance funds (statutory obligation), but also private health insurers (contractual obligation). The term IT security check is also new. Although this is not defined in the updated MPBetreibV, it is listed in §2 (1) No. 6 MPBetreibV as a sub-category of activities in connection with the operation and use of devices.「提供者」一詞是新增的。根據《醫療器材運作者條例》（MPBetreibV）第2（5）條，提供者是指任何負有法定或合約義務向患者提供產品的人。這可以是健康保險基金、意外保險基金和長期照護保險基金（法定義務），也可以是私人健康保險公司（合約義務）。

「資訊科技安全檢查」一詞也是新增的。雖然更新後的《醫療器材運作者條例》（MPBetreibV）並未對其進行定義，但《醫療器材運作者條例》（MPBetreibV）第2（1）條第6款將其列為與設備操作和使用相關的活動子類別。

4. The most important innovations regarding software as a medical device and IT security checks關於軟體作為醫療設備和 IT 安全檢查的最重要創新

According to §4 (3) MPBetreibV, instruction in the proper handling of the product is generally required. The new version of the MPBetreibV stipulates that this also applies to software after each installation of updates that change the handling of the software by the user during operation and use to more than a minor extent. § 17 MPBetreibV regulates special obligations when operating and using software as a class IIb and III medical device and software as a class C and D IVD. Similar to certain active products, §11 MPBetreibV, the proper installation of this software must be checked beforehand and a person authorized by the operator must be instructed. 根據 MPBetreibV 第 4 條第 (3) 款，通常需要指導如何正確操作產品。新版 MPBetreibV 規定，此規定同樣適用於每次安裝更新後的軟體，這些更新會在操作和使用過程中對使用者的操作方式產生較大變更。 MPBetreibV 第 17 條規定，操作和使用 IIb 類和 III 類醫療器材軟體以及 C 類和 D 類體外診斷器材 (IVD) 軟體時應承擔的特殊義務。與某些主動產品類似，MPBetreibV 第 11 條規定，必須事先檢查軟體是否安裝正確，並由操作員授權的人員進行指導。This software may only be operated or used by persons who have been instructed as described above. When operating or using this software in healthcare facilities, an IT security check must be carried out every two years at the latest. Deadlines, date of performance, name of the person or company performing the test and the result must be recorded in the medical device log-book.本軟體僅可由接受過上述指導的人員操作或使用。在醫療機構中操作或使用本軟體時，必須至少每兩年進行一次 IT 安全檢查。檢查截止日期、執行日期、執行測試的人員或公司名稱以及結果必須記錄在醫療器材日誌中。

It should be noted that the obligations of §17 MPBetreibV do not apply to software as a Class I and IIa medical device or to software as a Class A and B IVD. §17 MPBetreibV shall apply from 1 August 2025.需要注意的是，§17 MPBetreibV 的義務不適用於 I 類和 IIa 類醫療器材軟體或 A 類和 B 類 IVD 軟體。 §17 MPBetreibV 自 2025 年 8 月 1 日起適用。

5. Changes to maintenance維護變更

Maintenance remains regulated in §7 MPBetreibV. What is new is the explicit operator obligation for maintenance, §7 (1) sentence 1 MPBetreibV. In the opinion of the BMG, however, this is only a clarification. 維護仍受《道路交通法典》（MPBetreibV）第7條的約束。新規定明確了業者的維護義務，即《道路交通法典》第7條第1款第1句。然而，德國道路交通管理局（BMG）認為，這只是一項澄清。

If a product is in the possession of a patient, the maintenance obligation is reduced to a notification obligation. The patient's legal entitlement to maintenance and the corresponding deadlines must be notified, § 7 (1) sentence 2 MPBetreibV. The system and definition of the term “maintenance” have also been adapted. According to § 7 (2) sentence 1 MPBetreibV, maintenance includes in particular servicing and inspections that are necessary to ensure safe and proper product operation, as well as repairs to restore the functionality of a product. 如果產品由患者持有，則維護義務將簡化為通知義務。必須通知病人其享有的維護權利及相應的期限（MPBetreibV 第 7 條第 1 款第 2 句）。 「維護」一詞的系統和定義也已調整。根據 MPBetreibV 第 7 條第 2 款第 1 句，維護尤其包括為確保產品安全正常運作所需的維修和檢查，以及為恢復產品功能而進行的維修。

6. Reprocessing of reusable products vs. reprocessing of single-use products可重複使用產品的再加工與一次性產品的再加工

With the update of the MPBetreibV, the legal requirements for the reprocessing of medical devices can now be found in two separate regulations of the MPBetreibV.隨著 MPBetreibV 的更新，現在可以在 MPBetreibV 的兩個單獨法規中找到有關醫療器材再處理的法律要求。

§ 8 MPBetreibV now regulates the reprocessing of reusable devices. The heading reads accordingly: *Reprocessing of devices, with the exception of single-use devices*. Little has changed in terms of content. Only a provision has been added that allows the option of voluntary certification of the quality management system, §8 (3) sentence 2 MPBetreibV. Without this addition, voluntary certification would no longer have been possible in future for formal reasons.現將《MPBetreibV》第8條應用於可重複使用器械的再處理。標題改為：器械的再處理，一次性器械除外。內容方面變化不大。僅新增了一項條款，允許對品質管理系統進行自願認證，即《醫療器材運作者條例》第8條第3款第2句。若無此項新增條款，基於形式上的原因，未來將無法進行自願認證。

By moving the provisions on the reprocessing of single-use devices to §9 MPBetreibV, the former §8 (7) MPBetreibV has now (again) become §8 (4) MPBetreibV.

§ 9 MPBetreibV regulates the reprocessing and reuse of single-use devices. These regulations correspond to the §8 (4) to (6) MPBetreibV valid in the period from 26.05.2021 to 19.02.2025. These regulations can now be found in §9 (1) to (3) MPBetreibV. §9 (4) MPBetreibV regulates qualification requirements analogous to §8 透過將有關一次性器械再處理的規定移至《醫療器材運作者條例》（MPBetreibV）第9條，原第8條第7款現已（再次）變為第8條第4款。

§ 第9條規定了一次性器械的再處理和再利用。這些規定與2021年5月26日至2025年2月19日期間有效的第8條第4款至第6款相對應。這些規定現位於第9條第1款至第3款。第9條第4款規定了與第8條類似的資格要求。

(4) MPBetreibV with a link to the special requirements regulated in §5 MPBetreibV. MPBetreibV 第4款與 MPBetreibV 第5條 規定的特殊要求有關。

Accordingly, the reprocessing of single-use devices is still permitted in Germany in accordance with Art. 17 para. 3 and 4 MDR with reduced manufacturer obli-gations in compliance with the Implementing Regulation (EU) 2020/1207 (definition of common specifications for the reprocessing of single-use devices) and the KRINKO-BfArM recommendation.因此，根據 MDR 第 17 條第 3 款和第 4 款，德國仍允許對一次性設備進行再處理，同時減少製造商的義務，以符合實施條例 (EU) 2020/1207（一次性設備再處理的通用規範定義）和 KRINKO(醫院衛生與感染預防委員會 Commission for Hospital Hygiene and Infection Prevention)-BfArM(聯邦藥品醫療器材研究所Federal Institute for Drugs and Medical Devices)建議。

However, CE reprocessing is also still permitted in Germany. The ban demanded by the Federal Council was not implemented in the MPBetreibV. It was *already* pointed out in the materials for the Medical Devices EU Adaptation Ordinance (MPEUAnpV) that otherwise – i.e. outside the exemption options pursuant to Art. 17 para. 3 and 4 MDR – a natural or legal person who reprocesses a single-use device would remain subject to the obligations of a manufacturer under the MDR pursuant to Art. 17 para. 2 MDR [7]. 然而，在德國，CE 再處理仍然是允許的。聯邦委員會要求的禁令並未在 MDR 中實施。 《歐盟醫療器材適應性條例》（MPEUAnpV）的資料中已經指出，否則－即在 MDR 第 17 條第 3 款和第 4 款規定的豁免選項之外－再處理一次性醫療器材的自然人或法人仍將根據 MDR 第 17 條第 2 款承擔製造商的義務[7]。

In the materials accompanying the draft revision of the MPBetreibV, it was pointed out that the provisions served to clarify that both CE reprocessing and reprocessing in accordance with Art. 17 para. 3 MDR are permissible in Germany [8]. In addition, Germany has notified the European Commission of the permissibility of reprocessing single-use devices in accordance with both Art. 17 para. 2 MDR and Art. 17 para. 3 and 4 MDR [9]. Finally, CE reprocessing was already permitted in Germany under Directive 93/42/EEC. At that time, CE reprocessing was a *full refurbishment* according to Directive 93/42/EEC. The first certificates for this were issued by notified bodies in 2011.在 MPBetreibV《醫療器材運作者條例》修訂草案的隨附資料中，指出這些規定旨在明確在德國允許進行 CE 再處理和根據 MDR 第 17 條第 3 款進行再處理 [8]。此外，德國已通知歐盟委員會，允許根據 MDR 第 17 條第 2 款和第 17 條第 3 款和第 4 款對一次性使用器械進行再處理 [9]。最後，根據 93/42/EEC 指令，CE 再處理已在德國獲得允許。當時，根據 93/42/EEC 指令，CE 再處理屬於全面翻新。第一批此類證書由公告機構於 2011 年頒發。

7. Return of the obligation to affix signs in accordance with STK and MTK回歸依照 STK 和 MTK 貼上標誌的義務

It is beyond the scope of this short article to describe the changes to STK and MTK, particularly in the area of automatic external defibrillators and the simplifications for measuring devices for non-invasive blood pressure measurement. It should only be pointed out at this point that the obligation to affix signs in accordance with STK and MTK has returned in accordance with §12 (3) sentence 1 no. 2 MPBetreibV and §15 (7) sentence 1 no. 2 MPBetreibV. 本文不便詳述 STK 和 MTK 的變更，尤其是在自動體外心臟去顫器領域，以及無創血壓測量設備的簡化。在此僅需指出，根據 MPBetreibV **《醫療器材運作者條例》**第 12 條第 3 款第 1 句第 2 項和 MPBetreibV《醫療器材運作者條例》第 15 條第 7 款第 1 句第 2 項的規定，根據 STK 和 MTK 貼上標誌的義務已恢復。

8. Conclusion結論

An amended MPBetreibV has been in force since 20.02.2025. The most important changes were discussed in this short article.經修訂的《MPBetreibV》《醫療器材運作者條例》已於2025年2月20日起生效。本文探討了其中最重要的變化。

The smaller changes, e.g. in §§ 1, 4 to 6, 10, 11, 16, 18, 20 f. MPBetreibV could not be dealt with here. Readers are advised to read the text of the ordinance to form their own impression of the changes. At this point, it should also be noted that with the update of the MPBetreibV, the administrative offenses subject to fines regulated in § 19 MPBetreibV have also been adapted. It is not yet clear when the MPBetreibV will be amended again. However, changes are conceivable with regard to operator obligations resulting from the European Regulation (EU) 2024/1689 on artificial intelligence (AI Act, AI Regulation).
較小的變化，例如§§1、4至6、10、11、16、18、20 f. MPBetreibV《醫療器材運作者條例》無法在此處理。建議讀者閱讀條例文本，以形成對變化的理解。
此時也應注意，隨著 MPBetreibV《醫療器材運作者條例》的更新，第 19 條 MPBetreibV《醫療器材運作者條例》中規定的應處以罰款的行政違法行為也已調整。目前尚不清楚 MPBetreibV 何時會再次修訂。但是，根據歐洲人工智慧法規 (EU) 2024/1689（《人工智慧法案》，《人工智慧法規》），運作者義務可能會發生變化。

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Maintaining the validator's knowledge維持確效者的知識

Robert Streller

Section 8 (4) of the Medical Devices Operator Ordinance (MPBetreibV) [2] requires: "The validation of the reprocessing process must be carried out by qualified specialists." But what exactly does "qualified" mean? This question arises anew for every operator when commissioning validations.《醫療器材運作者條例》（MPBetreibV）[2] 第8(4)條規定：「再處理過程的確效必須由合格的專業人員進行。」但「合格」究竟是什麼意思？每個操作人員在進行確效時都會再次面臨這個問題。

Section 5 (1) also requires proof of up to date specialist knowledge. But how can this proof be provided in a way that is comprehensible to the operator第5（1）條也要求提供最新的專業知識證明。但如何以操作員能夠理解的方式提供這種證明呢?

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DGSV® e.V.: Qualifications for validators [1]
With the framework curriculum "DGSV® e.V. [1] Qualification – Validation Course", a standardized, comprehensible proof of qualification was established. Course participants acquire in-depth knowledge of
DGSV® e.V.：確效員資格 [1]
透過「DGSV® e.V. (德國無菌供應協會)[1] 資格 - 確效課程」框架課程，我們建立了標準化、易於理解的資格證明。課程參與者將獲得以下方面的深入知識:

- the basics of validation確效的基礎知識
- Responsibility for validation確效責任.

They will also be able to他們還可以:

- Plan process validations for the reprocessing of medical devices規劃醫療器材再處理的流程確效
- Collaboration in the awarding of contracts合約授予的合作
- Interpretation and approval of validation reports確效報告的解釋和批准
- Implementing the identified measures實施已確定的措施

The framework curriculum of the DGSV® e.V. [1] includes, among other things DGSV e.V.(德國無菌供應協會) [1]的框架課程包括以下內容:

- Introduction to the topic主題介紹
- Process Validation Basics製程確效基礎知識
- Planning and organization of process validations規劃與組織流程確效
- Validation of cleaning and disinfection processes清潔和消毒過程的確效
- Validation of packaging processes包裝流程確效
- Validation of steam sterilization processes蒸氣滅菌過程確效
- Tasks after process validation has been carried out.完成製程確效後的任務。

The course is completed with a written examination in accordance with the current examination regulations of the DGSV® e.V. [1].本課程將根據 DGSV® e.V. (德國無菌供應協會) 的現行考試規定通過筆試完成。

History of the validation courses確效課程的歷史
As early as 2019, a certified course for the validation of steam sterilization processes was introduced – the Vali A (basics) and Vali B (performance qualification) modules.早在 2019 年，就推出了用於確效蒸氣滅菌過程的認證課程—Vali A（基礎知識）和 Vali B（性能確效）模組。

After the publication of DIN 58341 [4] in 2020, the structure and content were expanded. Since 2022, the DGSV [1] courses have also covered manu-al and mechanical cleaning-disinfection devices (washer-disinfectors/en-doscope-washer-disinfectors) as well as packaging processes.2020年DIN 58341 [4]發布後，其結構和內容得到了擴展。自2022年起，DGSV(德國無菌供應協會) [1] 課程還涵蓋了手動和機械清潔消毒設備（清洗消毒機/內視鏡清洗消毒機）以及包裝流程。

The modules at a glance模組一覽:

- Vali A: Basics of preparation準備的基礎知識
- Vali B: Performance Qualification of processing processes處理過程的性能確效
- Vali C1: Automated Thermal WD Processes自動化熱清洗消毒器washer-disinfectors (WD)流程
- Vali C2: Automated chemothermal WD processes自動化學熱清洗消毒器流程
- Vali C3: Manual cleaning and disinfection processes手動清潔和消毒過程
- Vali D: Packaging processes包裝流程
- Vali E: Steam sterilization processes蒸氣滅菌過程

The overall training lasts 20 days – the same length as the previous combination of FK I (15 days) and Module E (5 days整個訓練持續 20 天，與先前的 FK I（15 天）和 Module E（5 天）的組合長度相同。

This is the first specialized and structured training course for validators.這是第一個針對確效者的專業化、結構化的訓練課程。

Legal certainty for the operator運作者的法律確定性
The DGSV [1]-certified training courses provide clarity: it is possible to provide evidence of qualified specialists in accordance with § 8 Medical Devices Operator Ordinance [2].DGSV(德國無菌供應協會) [1] 認證的訓練課程提供了明確的資訊：可以根據醫療器材運作者條例第 8 條 [2] 提供合格專家的證據。
Continuous adaptation of the course content to the state of the art and applicable standards also ensures that knowledge is kept up to date.課程內容不斷適應最新技術和適用標準，也確保知識保持最新。

Maintaining up-to-date knowledge維持最新知識
While there are numerous training formats in the field of RUMED(The Reprocessing Unit for Medical Devices (RUMED)醫療器材再處理部門) (e.g. DGSV Congress [7], internal training courses), there have been no specific programs for validators to date.雖然 RUMED 領域有多種培訓形式（例如 DGSV(德國無菌供應協會) 大會 [7]、內部培訓課程），但迄今為止還沒有針對確效者的特定計劃。

At the same time, laws, standards and guidelines are constantly changing.同時，法律、標準和指導方針也在不斷變化。
So how can up-to-date knowledge be demonstrated那麼如何展現最新的知識呢?

Photo照片: Participants in the Berlin course柏林課程的參與者。.

The new Annex 2 to the 6th edition of the WD guideline [3], published on 1st July 2024, specifies for the first time2024 年 7 月 1 日發布的第 6 版 WD 洗消毒器washer-disinfectors (WD)指南 [3] 的新附件 2 首次規定:

- **Time-based基於時間:** at least every two years至少每兩年
- **Event-related事件相關:** in the event of changes to relevant regulations事件中相關法規發生變化

Suitable measures are, for example, refresher courses at recognized educational centres. These must comprise at least 8 teaching units, the course content must be registered with the DGSV 適當的措施包括，例如在認可的教育中心進行進修課程。這些課程必須至少包含8個教學單元，課程內容必須在DGSV(德國無菌供應協會) 註冊[1]. Participants will receive a certificate of participation.參與者將獲得參與證書。
Validating institutions with certification according to ISO 13485 [5] or accreditation according to ISO 17025 [6] are obliged to keep the specialist knowledge of their employees up to date anyway. 獲得 ISO 13485 [5] 認證或 ISO 17025 [6] 認可的確效機構有義務保持其員工的專業知識保持最新。

Since 2025, the DGSV [1] has offered the opportunity of having refreshers officially recognized. The first course will take place in Berlin in July 2025. Certificates of par-ticipation bear the label “recognised training”.自2025年起，德國無菌供應協會（DGSV）[1] 提供官方認可的進修課程。首期課程將於2025年7月在柏林舉行。參與證書上會標註「認可培訓」。

Refresher複習

The DGSV [1] offers the opportunity to have the refresher recognized. The first course of this kind took place in July 2025 in Berlin (Photo).德國無菌供應協會（DGSV）[1] 提供認可的進修課程。首屆此類課程於2025年7月在柏林舉辦（照片）。
The event was labelled as “recognized further training” on the certificate of attendance.活動在參加證書上被標記為「認可的進修」。

Conclusion結論

The DGSV [1] validation course provides in-depth training that ensures the qualification and expertise of validators. DGSV [1] (德國無菌供應協會)確效課程提供深入的培訓，確保確效人員的資格和專業知識。
The DGSV [1] refresher course is the first structured opportunity to regularly refresh specialist knowledge. For operators, this provides a legally secure basis for commissioning suitable validators in accordance with §§ 5 and 8 Medical Devices Operator Ordinance [2]. DGSV [1] (德國無菌供應協會)進修課程是定期更新專業知識的首個結構化機會。對於操作人員而言，這為根據《醫療器材操作人員條例》第 5 和 8 條 [2] 委託合適的確效人員提供了法律保障。

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Validated reprocessing processes: Where to find information on the validation frequency of processes in the washer-disinfector and steam sterilizer
經過確效的再處理流程：在哪裡可以找到有關清洗消毒器和蒸氣滅菌器流程確效頻率的信息

Stella Nehr-Werner, Ulrike Weber

Validation, as the term is colloquially used for the regular testing of reprocessing processes for effectiveness and reproducibility, is made up of various tests and is carried out in its entirety as (initial) validation when a new device is installed. According to DIN EN ISO 11139, validation (formerly initial validation) is defined as "the process of confirming, by providing objective evidence, that the requirements for a specific intended use or application have been met". In the area of reprocessing processes, it is made up of installation, operational and performance qualification. 確效，這個術語通常用來指對再處理過程的有效性和可重複性進行定期測試，它由各種測試組成，並且在安裝新設備時作為（初始）確效完整地執行。根據 DIN EN ISO 11139 標準，確效（以前稱為初始確效）定義為「透過提供客觀證據，確認已滿足特定預期用途或應用要求的流程」。在再處理製程領域，確效包括安裝、操作和性能確認。

These terms are defined in DIN EN ISO 11139 [8]. In Germany, they are enshrined in law in Section 8 of the Medical Devices Operator Ordinance, which stipulates that medical devices may only be reprocessed using validated procedures. The KRINKO/BfArM recommendation and the relevant standards for sterilizers or washer-disinfectors (WDs) provide further information on the implementation of validation and acceptance criteria. 這些術語在 DIN EN ISO 11139 [8] 中有定義。在德國，這些術語被納入《醫療器材運作者條例》第 8 條，該條例規定醫療器材只能使用經過確效的程序進行再處理。KRINKO/BfArM (醫院衛生與感染預防委員會(KRINKO)/德國聯邦藥品和醫療器材研究所 (BfArM))建議以及滅菌器或清洗消毒器 (WD) 的相關標準提供了有關實施確效和驗收標準的進一步資訊。For sterilization, these are DIN EN 13060 for small steam sterilizers, DIN EN 285 for large steam sterilizers and ISO 17665-1 for proof of sterilization performance, and for washer-disinfectors the DIN EN ISO 15883 series and DIN 58341. Furthermore, more specific information can be found in the guidelines of the DGSV, DGKH and AKI as well as in the guidelines of specific professional associations, such as the DAHZ hygiene guidelines for dentistry.

Validation therefore comprises several different process tests. These tests also check the environmental conditions and process-influencing parameters at the medical device operator's premises and confirm correct interaction. Validation and its regular repetition is therefore an important step in terms of infection prevention and patient and user protection. This approach places a clear emphasis on the control of the process and not on an exclusive product control (e.g. by means of microbiological tests or cleaning indicators). 對於滅菌，小型蒸氣滅菌器遵循 DIN EN 13060 標準，大型蒸氣滅菌器遵循 DIN EN 285 標準，滅菌性能證明遵循 ISO 17665-1 標準，而對於清洗消毒器，則遵循 DIN EN ISO 15883 系列和 DIN 58341 標準。此外，更具體的資訊可參考 DGSV（德國醫療器材再處理協會）、DGKH（德國綜合健康與醫院衛生協會）和AKI（再處理工作小組）的指南，以及特定專業協會的指南，例如 DAHZ 牙科衛生指南。因此，確效包含多項不同的製程測試。這些測試還檢查醫療器材操作員場所的環境條件和影響過程的參數，並確認交互作用是否正確。因此，確效及其定期重複是預防感染、保護患者和使用者的重要步驟。這種方法明確強調製程控制，而不是單一的產品控制（例如透過微生物測試或清潔指示劑）。

Routine tests are recommended to accompany the process to create a continuous comparison with processes considered in the validation and to be able to identify process changes as a trend analysis at an early stage. Information and notes on the frequency of requalification can be found in various documents, which are described below.建議在製程過程中進行常規測試，以便與確效過程中考慮的製程進行持續比較，並能夠在早期階段識別製程變化，進行趨勢分析。有關重新驗證頻率的資訊和說明可在下文所述的各種文件中找到。

KRINKO/BfArM recommendation 2012 (tables in Annex 3 and 4)KRINKO/BfArM ((德國羅伯特・科赫研究所之) KRINKO(醫院衛生與感染預防委員會 Commission for Hospital Hygiene and Infection Prevention)-BfArM(聯邦藥品醫療器材研究所Federal Institute for Drugs and Medical Devices))2012 年建議（附件 3 和 4 中的表格）

The KRINKO/BfArM recommendation from 2012 provides information on the requalification in the tables KRINKO/BfArM(醫院衛生與感染預防委員會(KRINKO)/德國聯邦藥品和醫療器材研究所 (BfArM))建議自2012年在表格中提供了有關重新驗證的信息

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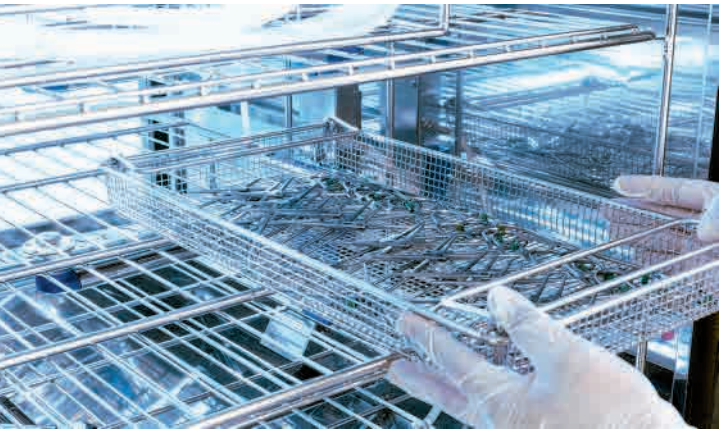
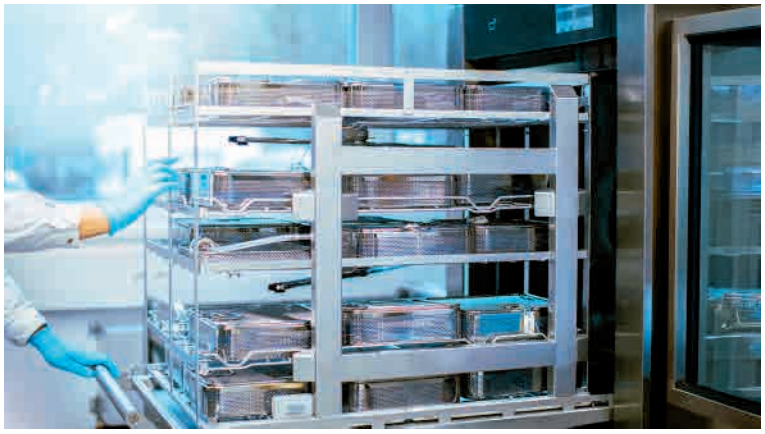
in Annexes 3 and 4. For a washer-disinfector, Annex 3: Commissioning and operation of washer-disinfectors for the reprocessing of medical devices (checklist) states that the acceptance test consists of installation qualification (IQ) and operational qualification (OQ) and that the suitability of the operating parameters is determined in the performance qualification (PQ). Under periodic inspections and procedure in the event of deviations from the regular process and relevant frame-work conditions, reference is made to the obligation of the operator and the validator, considering the manufacturer's specifications when determining the due date of periodic inspections (renewed performance qualification). Furthermore, the stability of the processes must be considered when determining the intervals. For small steam sterilizers, information on validation is provided in Annex 4: Commissioning and operation of small sterilizers for the reprocessing of medical devices (checklist). Reference is also made to the obligation of the operator and validator regarding requalification.在附件 3 和 4 中。對於清洗消毒器，附件 3：醫療器材再處理用清洗消毒器的調試和操作（清單）規定驗收測試包括安裝確效（IQ）和操作確效（OQ），並且操作參數的適用性在性能確效（PQ）中確定。在定期檢查和程序中，如果出現偏離常規流程和相關框架條件的情況，則參考操作員和確效員的義務，在確定定期檢查的到期日（更新的性能確認）時考慮製造商的規範。此外，在確定間隔時必須考慮過程的穩定性。對於小型蒸氣滅菌器，附件4：醫療器械再處理用小型滅菌器的調試和操作（清單）中提供了有關確效的資訊。也參考了操作員和確效員關於重新驗證的義務。

DIN EN ISO 15883-1

The horizontally relevant standard of the DIN EN ISO 15883 series (i.e. applicable to all special parts of the standard) [2] specifies the aspects in chapter 6.1.5 for the reassessment: DIN EN ISO 15883 系列的橫向相關標準（即適用於該標準的所有特殊部分）[2] 在第 6.1.5 章中規定了重新評估的面向:

- Modifications or technical work on the device and installation that may affect the performance of the washer-disinfector對設備和安裝進行的修改或技術工作可能會影響清洗消毒機的性能





- Deviations of the routine tests from the validation data常規測試與確效資料的偏差
- Insufficient performance of the WD清洗消毒機性能不足
- Changes to the process conditions流程條件的改變 (e.g. process chemicals流程化學品)
- At specified intervals依指定的時間間隔

Regarding the specified intervals, it is specifically mentioned that this can be determined by the competent authority or a risk analysis and that the normal practice is annual performance qualification. As DIN EN ISO 15883-1 is a harmonized European standard, these criteria therefore apply to all EU member states. The DIN EN ISO 15883-1 does not provide any further information on carrying out the risk analysis.關於規定的間隔，特別提到，這可以由主管機關或風險分析確定，並且通常的做法是每年進行一次性能鑑定。由於 DIN EN ISO 15883-1 是歐洲協調標準，因此這些標準適用於所有歐盟成員國。 DIN EN ISO 15883-1 沒有提供任何關於進行風險分析的更多資訊

Guideline指南 from DGKH(德國綜合健康與醫院衛生協會), DGSV(德國無菌供應協會) and AKI (再處理工作小組)

The guideline for the validation of automated processes [1] refers to the information on requalification of performance in chapter 5.4.自動化流程確效指南[1]引用了第5.4章中有關效能重新鑑定的資訊。

- The specified intervals in accordance with DIN EN ISO 15883-1 and thus for a renewed inspection without special cause at annual intervals and to justify any deviation from these intervals.依照 DIN EN ISO 15883-1 規定的間隔，因此，如果沒有特殊原因，每年需要重新進行檢查，並證明與這些間隔的任何偏差是合理的。
- If routine inspections reveal deviations from the validation data如果例行檢查發現與確效資料有偏差
- When introducing modified medical devices to be cleaned and disinfected or new load carriers, if no equivalence to a tested reference load or a validated medical device or loading system can be proven當導入經過修改的需要清潔和消毒的醫療設備或新的負載載體時，如果無法證明其與經過測試的參考負載或經過確效的醫療設備或負載系統等效
- In the event of changes to process chemicals如果流程化學品發生變化
- After maintenance work that may affect the performance of the washer-disinfector進行可能影響清洗消毒機性能的維護工作後

This information is supplemented and underpinned in the guideline by meaningful and practical appendices.該指南透過有意義且實用的附錄對這些資訊進行了補充和支持。

DIN EN 285/DIN EN 13060 /DIN EN ISO 17665

DIN EN 13060 refers directly to DIN EN ISO 17665 in 8.1 on the subject of testing sterilization performance. EN 285 also contains information on installation and operational qualification, but DIN EN ISO 17665 is also referred to for the description of testing sterilization performance, i.e. performance assessment. Chapter 9 of DIN EN ISO 17665 deals with validation and describes in detail which tests are included in the individual points of validation. There are no specific statements on reassessment of performance in this standard, but the stability of processes, routine monitoring and requalification are described. Requalification must be carried out for certain products at specified intervals if the criteria requiring requalification have been met. DIN EN 13060 在 8.1 部分關於滅菌性能測試的內容中直接引用了 DIN EN ISO 17665。 EN 285 也包含有關安裝和操作認證的信息，但 DIN EN ISO 17665 也用於描述滅菌性能測試（即性能評估）。 DIN EN ISO 17665 第 9 章涉及確效，並詳細描述了各個確效點包含哪些測試。該標準中沒有關於性能重新評估的具體說明，但描述了製程穩定性、常規監控和重新確效。如果符合重新認證的標準，則必須按照規定的時間間隔對某些產品進行重新確效。

Recommendation for the validation and routine monitoring of sterilization processes with saturated steam for medical devices醫療器材飽和蒸氣滅菌過程確效和常規監測建議 (DGKH德國綜合健康與醫院衛生協會) Due to the age of this recommendation, the terms “revalidation” and “reassessment” are not defined according to the current interpretation. Nevertheless, the inspection is the same routine inspection of the processes to ensure safe and stable steam sterilization in the sense of a validated reprocessing process. Accordingly, the topic of requalifiation is explained in Chapter 2 and the interval for requalifiation is specified as one year. The interval of one year can be extended for stable processes. “The period can be extended if the processes are constantly stable (e.g. daily batch testing, proof of reproducibility)” [12].由於該建議發佈時間較長，因此「再確效」和「再評估」這兩個術語尚未根據目前的解釋進行定義。然而，該檢查與常規檢查相同，旨在確保在經過確效的再處理過程中實現安全穩定的蒸氣滅菌。因此，第2章解釋了再確效的主題，並將再確效的間隔規定為一年。對於穩定的流程，一年的間隔可以延長。「如果製程始終保持穩定（例如每日批量測試、可重複性證明），則可以延長間隔」[12]。

DIN SPEC 58929 Operation of small steam sterilizers in the healthcare sector – Guidelines for validation and routine monitoring of sterilization processes DIN SPEC 58929 醫療保健領域小型蒸氣滅菌器的操作 - 滅菌過程驗證和常規監控指南

To prove that the sterilization process is effective over a longer period of time, DIN SPEC 58929 also lists routine checks as an important and suitable measure. Chapter 9.4.2 recommends carrying out a new performance assessment after a maximum of 2000 batches or one year. For small steam sterilizers according to EN 13060, the interval deviates from this and is specified as 4000 batches or 2 years (chapters 9.4.3 and 9.4.4) [13].為了證明滅菌過程在較長時間內有效，DIN SPEC 58929 也將例行檢查列為重要且適當的措施。第 9.4.2 章建議，最多在 2000 批或一年後進行一次新的效能評估。對於符合 EN 13060 標準的小型蒸氣滅菌器，間隔時間與此不同，規定為 4000 批或兩年（第 9.4.3 和 9.4.4 章）[13]

State-specific hygiene regulations各州特定的衛生法規

For North Rhine-Westphalia, a state-specific instruction "Requirements for the hygienic reprocessing of medical devices in North Rhine-Westphalia; status: 17.11.2023" [4] applies, which provides a very comprehensive overview of the requirements for automated cleaning and disinfection in Chapter 2. The following requirements are set regarding the requalification and the risk analysis is also carried out:對於北萊茵-威斯特法倫州，適用一項特定於州的指令"北萊茵-威斯特法倫州醫療器械衛生再處理要求：狀態：2023 年 11 月 17 日" [4]，該指令在第 2 章中對自動清潔和消毒的要求進行了非常全面的概述。針對再認證設定了以下要求，並進行了風險分析：

a) Performance qualification independent of events 獨立於事件的性能驗證

A requalification must always be carried out annually. Based on a risk analysis (e.g. ICH Q9, VDI 5700), the interval can be extended in justified individual cases on condition that the operator carries out an evaluation of the process after one year to assess whether it is stable and conforms to the specification. The period considers the maintenance interval of the washer-disinfector defined by the manufacturer and must not exceed 24 months. 每年必須進行一次重新驗證。基於風險分析（例如 ICH Q9、VDI 5700），在合理的情況下，可在個別情況下延長認證間隔，前提是操作員在一年後對製程進行評估，以評估其是否穩定且符合規範。此週期考慮了製造商規定的清洗消毒機維護間隔，且不得超過 24 個月。

b) Performance qualifications (including installation and functional qualifications, if applicable) for special reasons 因特殊原因而進行的性能驗證（包括安裝和功能驗證，如適用）

- if changes or technical work have been made to the device and installation that could impair the performance of the WD 如果對設備和安裝進行了更改或技術工作，可能會損害清洗消毒機WD 的性能;
- if the review of the records of routine tests on the performance of the WD reveals one or more unacceptable deviations from the data of the initial validation 如果對 清洗消毒機WD 性能例行測試記錄的審查發現與初始確效數據存在一個或多個不可接受的偏差
- if the performance of the WD is unacceptable 如果清洗消毒機WD 的性能不可接受
- if process conditions (e.g. process chemicals, water used) are changed.若製程條件（例如製程化學品、所使用的水）發生變化。

Also, in the "Guideline of the State of Baden-Wurttem-berg on the hygienic reprocessing of medical devices" (2019) [5] there is a note on the subject of requalification. Regarding frequency, it mentions "A reassessment must be carried out at specific intervals and, if necessary, for special reasons. For cleaning and disinfection processes, the interval is usually 1 year, for sterilization processes in small sterilizers up to 2 years. "此外，在《巴登-符騰堡州醫療器材衛生再處理指南》（2019年）[5]中，有關於再確效的說明。關於頻率，其中提到"必須按照特定時間間隔進行再評估，如有必要，也可出於特殊原因進行。清潔和消毒過程的再評估間隔通常為1年，小型滅菌器的滅菌過程的再評估間隔最長為2年。"

DAHZ Hygiene guideline衛生指南

The hygiene guidelines of the German Working Group for Hygiene in Dentistry (DAHZ) [7] describe the topics of validation and requalification in detail. According to this, the period for requalification is to be determined by the operator in collaboration with the validator following a risk analysis and considering the stability of the processes in the past. This takes place once a year, for example, and can be extended if processes are sta-ble (e.g. in combination with maintenance). In the event of anomalies in the routine inspections, the interval should be shortened. In practice, this joint approach has proven to be difficult, as the validator cannot be in the field for this joint risk assessment.德國牙科衛生工作小組 (DAHZ) [7] 的衛生指南詳細描述了確效和再驗證的主題。據此，再確認週期應由操作員與確效員共同決定，並根據風險分析和過去流程的穩定性進行。再確認週期例如每年一次，如果流程穩定（例如與維護相結合），則可以延長。如果例行檢查出現異常，則應縮短再確認週期。實務證明，這種聯合方法比較困難，因為確效員無法親自到現場進行聯合風險評估。

Further requirements for requalification are重新驗證的進一步要求是

- Repairs with replacement of process-relevant components維修更換與流程相關的零件
- Significant changes to the process.流程發生重大變化

If regular maintenance is carried out in accordance with the manufacturer's instructions, requalification can be carried out independently of maintenance.如果按照製造商的說明進行定期維護，則可以獨立於維護進行重新驗證。

Risk analysis風險分析

The literature sources already mentioned include risk analysis as a suitable measure for extending the frequency of validation. This is explained in more detail below.

A risk analysis is the search for hazards and the estimation of the probabilities and severity of the resulting damage. When the term risk analysis is used, it often refers to a hazard analysis. According to ISO 14971 [9], this is a common process for manufacturers of medical devices in the course of product development and during the life cycle management of medical devices. VDI 5700 entitled "Hazards during reprocessing – Risk management during the reprocessing of medical devices – Measures for risk control" [3] is a highly recommended document for carrying out a risk analysis. There are very good and subject-specific templates especially for the dental sector and risk analyses in this specialist discipline, e.g. from the regional dental associations.已提及的文獻資料表明，風險分析是延長確效頻率的合適方法。下文將對此進行更詳細的解釋。風險分析是指尋找危險並評估由此造成的損害的機率和嚴重程度。「風險分析」一詞通常指危害分析。根據 ISO 14971 [9]，這是醫療器材製造商在產品開發和醫療器材生命週期管理過程中的常用流程。 VDI 5700 標準《再處理過程中的危害－醫療器材再處理過程中的風險管理－風險控制措施》[3] 是一份強烈建議的風險分析文件。目前，有一些非常好的、針對特定主題的模板，尤其適用於牙科領域和該專業領域的風險分析，例如來自地區牙科協會的模板。

The DGSV recommendations of the "Quality Task Group" [10] deal with the topic of "Risk management in the RUMED" and thus provide users with a very good guide to risks and the corresponding assessment. 德國無菌供應協會(DGSV)「品質工作小組」[10]的建議涉及「RUMED(醫療器材再處理單位Reprocessing Units for Medical Devices)中的風險管理」主題，從而為使用者提供了非常好的風險和相應評估指南。

Relevance of the maintenance frequency of washer-disinfectors/sterilizers in relation to performance qualification 清洗消毒器/滅菌器的維護頻率與性能驗證的相關性

The maintenance frequency of the devices used (washer-disinfectors and sterilizers) is frequently mentioned in risk assessments. The risk-based maintenance specifications of the respective manufacturers therefore represent a reliable statement on the minimum reliability of a process, provided that the process is carried out within the framework of the manufacturer's intended specifications. Nevertheless, it should be noted that a process should be equally stable before and after maintenance. 風險評估中經常提及所用設備（清洗消毒機和滅菌器）的維護頻率。因此，只要流程在製造商規定的規範框架內執行，各製造商基於風險的維護規範就能可靠地保證流程的最低可靠性。然而，需要注意的是，流程在維護前後應保持同等穩定性。

Routine checks as stability criteria in relation to the process例行檢查作為與流程相關的穩定性標準

It is striking that the routine checks are frequently mentioned. This is due to the fact that they provide essen-tial information about the processes. Routine checks are both technical (e.g. checking machine spray arms and the spray arms of the trolleys and baskets, regular Check & Clean) and batch-related (e.g. pH test for ophthalmic instruments, process monitoring indicators, measurement of the NCG content). 引人注目的是，例行檢查被頻繁提及。這是因為它們提供了有關流程的重要資訊。例行檢查既包括技術性檢查（例如，檢查機器噴臂、推車和籃子的噴臂，定期檢查和清潔），也包括批次相關檢查（例如，眼科器械的pH值測試、流程監控指標、NCG(不凝性氣體Non-Condensable Gas)含量測量）。

They form an important pillar of the stability criteria, which are necessary for a well-running process and its monitoring. There are also literature sources for this in the KRINKO/ BfArM recommendation point 1.4) and for the definition of the term in DIN EN ISO 11139 under point 3.238: "periodically performed technical process to establish whether the operational performance of the equipment or process is within the limits determined during validation".它們構成了穩定性標準的重要支柱，對於流程的良好運作及其監控至關重要。
KRINKO/BfArM (醫院衛生與感染預防委員會(KRINKO)/德國聯邦藥品和醫療器材研究所 (BfArM))建議第 1.4 點以及 DIN EN ISO 11139 第 3.238 點對該術語的定義也提供了相關文獻：「定期執行的技術流程，以確定設備或工藝的運行性能是否在確效過程中確定的限值範圍內」。
The DGSV recommendation of the "Quality Task Group" "Routine tests for monitoring the automated cleaning and disinfection process" [11] provides practi-cal information on batch-related and periodic tests. Routine checks are also specified in the standards, for example DIN EN ISO 17665-1 in chapter 10.1 contains in-formation on routine monitoring of the sterilization process using chemical indicators and/or PCD tests. This is intended to monitor steam penetration and provide another independent parameter as a control point in addition to the physical sensors installed on the appliance. DIN EN ISO 15883-1 refers to the importance of rou-tine tests in Appendix A; the description of the contents can be found in Table A.1 Summary of test programs for washer-disinfectors. The importance of routine checks can be deduced from the scope of the content. DGSV(德國無菌供應協會）「品質工作小組」的建議《用於監控自動清潔和消毒流程的常規測試》[11]提供了批次相關測試和定期測試的實用資訊。常規檢查在標準中也有規定，例如，DIN EN ISO 17665-1 第 10.1 章包含使用化學指示劑和/或 PCD 測試對滅菌過程進行常規監控的資訊。這旨在監控蒸汽滲透情況，並提供除設備上安裝的物理感測器之外的另一個獨立參數作為控制點。 DIN EN ISO 15883-1 在附錄 A 中提到了常規測試的重要性；其內容描述請參閱表 A.1「清洗消毒器測試程序摘要」。常規檢查的重要性可以從其內容範圍推斷出來。

Staff as a stability criterion員工作為穩定性標準

All sources refer to process stability to correctly determine the validation frequency. These should be closely monitored through routine checks and confirmed during validation or requalification. But what decisive influence does the human factor have? And how can it become a stability criterion for processes? On the one hand, only qualified personnel are used in reprocessing, which is regulated by law and firmly anchored in the Medical Devices Operator Ordinance. This ensures good training and sufficient basic knowledge about reprocessing. Basic knowledge of validation should also be available. Nevertheless, there are subject areas that are specific to the practice and can only be learned on site. In addition to the practice-specific processes, the available equipment and the practice-specific selection of cleaning agents and disinfectants, this also includes the individual loading patterns and the definition of routine checks. Here, it is helpful to design the work instructions in such a way that they are simple and easy to understand and can also be read and understood on your own if necessary. 所有資料都參考了製程穩定性來正確地決定確效頻率。這些應該透過例行檢查進行密切監控，並在確效或再確效期間確認。但是，人為因素有哪些決定性的影響？它如何成為製程的穩定性標準？一方面，只有合格的人員才能再處理，這受到法律的監管，並在《醫療器材運作者條例》中穩固確立。這確保了良好的培訓和足夠的再處理基礎知識。確效的基礎知識也應該具備。然而，有些主題是特定於實踐的，只能在現場學習。除了特定於實踐的流程、可用的設備以及特定於實踐的清潔劑和消毒劑的選擇之外，這還包括個性化的裝載模式和例行檢查的定義。在這裡，設計簡單易懂的工作說明會很有幫助，如果需要，您也可以自己閱讀和理解。

Pictures are a valuable addition. This is the only way to ensure a smooth transition in the event of staff changes, vacation or sick leave. Ultimately, it also ensures the stability of processes if procedures are always designed and carried out in the same way. The precise definition of competencies and responsibilities also plays a major role. If it is known exactly who does what, errors are prevented, duplication of activities is avoided and forgotten tasks are largely eliminated.圖片是寶貴的補充。這是確保人員變動、休假或病假時順利過渡的唯一方法。最終，如果流程始終以相同的方式設計和執行，它也能確保流程的穩定性。職責和能力的精確定義也扮演著重要角色。如果明確每個人的職責，就能避免錯誤，避免重複工作，並在很大程度上避免任務被遺忘。

Who can carry out risk assessments to extend the validation interval誰可以進行風險評估以延長確效間隔?

This can only be done by the operator in their role as the person responsible for the reprocessing process and with the corresponding knowledge of the facility-specific procedures, the implementation of routine checks and the stability of the processes這只能由操作員作為後處理過程的負責人來完成，並且需要具備設施特定程序、例行檢查的實施和過程穩定性的相應知識.

Summary摘要

Validation or requalification is not a necessary obligation, but a crucial aspect of recording the performance of reprocessing processes on site. As within the entire medical technology industry, a balance must be struck between risk and safety. It is therefore possible to extend the frequency of validation based on a risk-based approach. 確效或再確效並非必要義務，但卻是記錄現場再處理流程績效的關鍵環節。如同整個醫療技術產業一樣，必須在風險與安全之間取得平衡。因此，可以基於風險導向的方法延長確效頻率。

The stability of the processes and therefore process safety is a central aspect of all specifications or recommendations for expansion. By defining stability criteria and ensuring strict compliance, it can be objectively documented (e.g. through routine checks) that processes are demonstrably stable between performance assessments.製程的穩定性以及由此帶來的製程安全性是所有擴展規範或建議的核心。透過定義穩定性標準並確保嚴格遵守，可以客觀地記錄（例如透過例行檢查）製程在性能評估期間的穩定性。

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The technical paper must be available in a short version - a 1 - 2 page summary is ideal. Furthermore, the author should be named with a picture and full name.技術論文必須提供簡短版本，最好有1-2頁的摘要。此外，也應註明作者姓名（附照片和全名）。

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Experience report on modern hygiene training courses
現代衛生訓練課程體驗報告
Designing hygiene training courses: Lively, practical, motivating設計衛生訓練課程：生動、實用、激勵

Ines Liebig

From my many years of professional experience as a freelance lecturer in the field of hygiene and reprocessing of medical devices, I would like to introduce you to a few training courses. How can participants be motivated? Hygiene training should not be a chore. They can be inspiring, interactive and relevant to everyday life. The aim is to avoid mistakes, reduce uncertainty and create a routine. 憑藉我多年在醫療器材衛生和再處理領域擔任自由講師的專業經驗，我想向您介紹一些培訓課程。如何激勵學員？衛生培訓不應該是枯燥乏味的。它們可以富有啟發性、互動性強，並與日常生活息息相關。其目的是避免錯誤，減少不確定性，並養成規律。

Sometimes it helps to boldly try out new things. I have given training courses in which I explained enveloped and non-enveloped viruses with chestnuts or surprise eggs – in a playful, visual and comprehensible way. After all, knowledge can only be implemented in everyday life if it sticks. 有時，大膽嘗試新事物會有所幫助。我曾在訓練課程中用栗子或驚喜雞蛋來解釋包膜病毒和無包膜病毒—以一種有趣、直觀且易於理解的方式。畢竟，知識只有紮根於日常生活中才能付諸實踐。

Who do we need to reach我們需要聯繫誰?

Our target groups are diverse: whether nursing staff, doctors, cleaning staff, management, relatives, external service providers or patients and visitors – each group needs to be addressed individually. If you want to embed hygiene in the long term, you have to adapt to different learning habits.
How do different generations learn? Each age group has different learning methods. Modern training concepts should take this into account我們的目標群體多樣化：無論是護理人員、醫生、清潔人員、管理人員、親屬、外部服務人員，還是病人和訪客—每個群體都需要個人化服務。想要長期培養衛生習慣，就必須適應不同的學習習慣。

不同世代的人如何學習？每個年齡層的人都有不同的學習方法。現代培訓理念應該考慮到這一點:

1. Baby boomers嬰兒潮世代 (approx.約莫 1946–1964)

- Prefer structured training courses偏好結構化的訓練課程
- Like face-to-face events with experts喜歡與專家面對面交流
- Enjoy learning from experience and specialist literature享受從經驗和專業文獻中學習的樂趣
- Practical example實際範例: a live training course with real case studies包含真實案例研究的現場培訓課程

2. Generation X 世代(approx. 約莫1965–1980)

- Like efficient, time-saving training courses喜歡高效率、省時的培訓課程
- Like to use e-learning & self-learning modules喜歡使用電子學習和自學模組
- Practical example實際範例： A modular online training course with short units包含短單元的模組化線上培訓課程

3. Generation Y 世代(approx. 約莫1981–1996, Millennials)

- Mobile learning行動學習
- Favour digital training, apps, gamification青睞數位化培訓、應用程式和遊戲化
- Practical example實際範例: A hygiene app with quiz questions and challenges一款包含測驗和挑戰的衛生應用程式

4. Generation Z 世代(approx. 約莫1997–2012)

- Learning through videos, interactive graphics, social media 透過影片、互動式圖形、社群媒體學習
- Prefers microlearning in the form of short, quickly consumable units喜歡簡短、快速易懂的微學習單元
- Practical example實際範例: approx. 60-second explanatory videos for social media約 60 秒的社交媒體解釋視頻

5. Generation Alpha 阿爾法世代(approx.約莫 2013– today)

- Learning with AI, virtual reality & augmented reality 利用人工智慧、虛擬實境和擴增實境進行學習(AR)
- Practical example實際例子: Interactive learning worlds in which microorganisms are made visible. 微生物可見的互動式學習世界。

Designing modern hygiene training programmes/practical relevance as the key to success
設計現代衛生培訓計劃/實踐相關性是成功的關鍵

Theoretical knowledge only sticks if it can be applied in practice. Training courses must be realistic. Learning through experience in the form of workshops with simulations and case studies is more effective than frontal teaching. Workshops offer the opportunity to apply theoretical knowledge in a protected environment and to recognise mistakes. 理論知識只有應用於實務才能發揮作用。培訓課程必須切合實際。透過模擬和案例研究等形式的研討會，透過實作學習比面對面授課更有效。研討會提供了在安全環境下應用理論知識並識別錯誤的機會。

Examples of practical training courses實際培訓課程範例:

- **Hand hygiene workshop**: use of fluorescent gel or UV light, DesiCoach, finger paint to make the "tightness" of the gloves visible手部衛生研討會：使用螢光凝膠或紫外線、DesiCoach、手指畫顏料，使手套的「緊密度」可見,
- **Handling PPE (personal protective equipment)**: Correct donning and doffing techniques of protective gowns, gloves, masks; use of fluorescent gel or UV light, DesiCoach, finger paint.處理 PPE（個人防護裝備）：正確穿戴和脫下防護衣、手套、口罩的技術；使用螢光凝膠或紫外線、DesiCoach、手指畫顏料。
- **Simulation of infection chains**: Interactive exercises to detect and prevent pathogen transmission in patient rooms or operating theatres using fluorescent gel感染鏈模擬：使用螢光凝膠進行互動練習，以檢測和預防病房或手術室中的病原體傳播 (Fig圖. 1)
- **Checking cleaning and disinfection quality**: Using hygiene test methods, such as ATP measurements, to make microbiological contamination visible; Hytrain®, Glow Check**檢查清潔和消毒品質：使用衛生測試方法，例如 ATP (三磷酸腺苷) 測量，使微生物污染可見；Hytrain®、Glow Check**
- **An interactive hygiene escape room**: instead of dry theory, staff are immersed in a fictitious but realistic situation: a patient with an unknown infection presents the team with a challenge.• 互動式衛生逃脫室：工作人員不再沉浸於枯燥的理論，而是沉浸在一個虛構但現實的情境中：一名感染未知疾病的患者給團隊帶來了挑戰。

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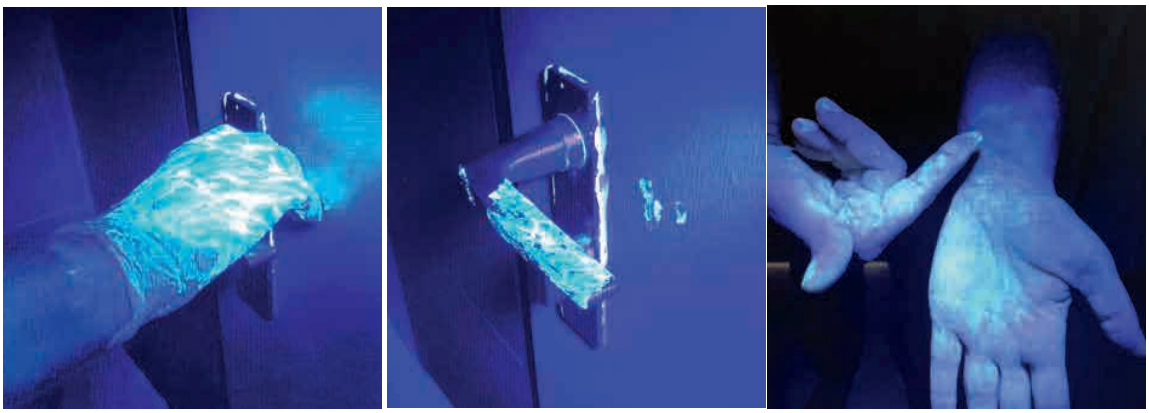

Fig圖. 1: The simulation shows how a pathogen spreads through a hospital – from the door handle to an employee's hand and then to the next patient.模擬顯示了病原體如何在醫院內傳播— 從門把手到員工的手，再到下一位病人。

Only those who know and apply the correct hygiene measures can stop the spread of the pathogen. Puzzling together, finding the mistakes and experiencing the consequences creates an awareness that remains in the memory 只有了解並採取正確的衛生措施，才能阻止病原體的傳播。共同思考，發現錯誤，並體驗後果，才能創造一種銘刻在記憶中的意識。

- **A workshop on hand hygiene under the motto "Make it naked"以「赤裸裸」為主題的手部衛生研討會**: "Make it naked" refers to hands without jewellery「赤裸裸」指的是手上不戴首飾(Fig圖. 2). A copy of a ring and watch is used as an example. For staff, visitors and patients, this creates additional awareness that can be taken home and passed on.以戒指和手錶的複製品為例。對於員工、訪客和患者來說，這可以增強他們的意識，並帶回家同時傳遞下去。
- **Poster Microorganisms海報微生物**: you can't see, smell or taste them – you only feel their presence after an infection.你看不見、聞不到、嚐不到它們—只有在感染後才能感覺到它們的存在。
- **When gloves really make sense當手套真正發揮作用時**: A look at everyday life. Many people wear gloves in situations where they are more of a danger. A comparison with everyday situations makes the problem clear: who would walk around in ski gloves all day without taking them off once? Nobody, because you sweat in them and the material eventually becomes unhygienic. Similarly, disposable gloves should not be worn for hours without being changed and without carrying out hygienic hand disinfection. Anyone who really takes hygiene seriously must not only disinfect their hands but also understand when protection makes sense and when it does more harm than good.看看日常生活。許多人在更危險的情況下戴手套。與日常生活對比一下，問題就顯而易見了：誰會整天戴著滑雪手套走來走去，一次也不脫？沒有人會，因為手套會流汗，手套的材質最終會變得不衛生。同樣，一次性手套不應該連續戴幾個小時而不更換，也不應進行衛生的手部消毒。任何真正重視衛生的人不僅要滅菌雙手，還要了解何時防護有效，何時防護弊大於利。

What could the future look like未來會是什麼樣子？?

Visions/future digitalisation願景/未來數位化 – are you ready你準備好了嗎? Breaking away from old ways and allowing new ways offers opportunities to use the new possibilities correctly.擺脫舊方式並允許新方式提供了正確利用新可能性的機會。

Involving patients and visitors 讓病人和訪客參與

Patients and visitors also play a crucial role in infection control. But many feel unsure: When should I sanitise my hands? Are gloves really necessary? And why are certain rules so strict? Instead of complicated information brochures, simple, understandable and entertaining concepts can help. 病人和訪客在感染控制中也發揮著至關重要的作用。但許多人感到困惑：什麼時候該消毒我的手？真的有必要戴手套嗎？為什麼某些規定如此嚴格？與其使用複雜的資訊手冊，不如使用簡單易懂、趣味盎然的概念。

- Patient TV as a training medium. Short videos similar to the welcome clips in hotels could be shown on the TV screens in patients' rooms. In just a few minutes, they show how proper hand disinfection works, why visitors should disinfect their hands when entering the ward or which small measures can have a big impact in everyday life. One hospital has integrated an interactive patient TV system that automatically plays a short training video on hand hygiene on admission. After the video, patients can answer a question via touchscreen (When should I disinfect my hands in hospital?).病房電視作為訓練媒介。可以在病房的電視螢幕上播放類似飯店歡迎影片的短片。短短幾分鐘內，這些影片展示了正確的手部消毒方法、訪客進入病房時為何需要消毒雙手，以及哪些小措施可以在日常生活中發揮重要作用。一家醫院整合了互動式病房電視系統，可在入院時自動播放一段簡短的手部衛生訓練影片。觀看完影片後，患者可以透過觸控螢幕回答問題（在醫院，我應該何時進行手部滅菌？）。
- Children's hospital兒童醫院: Children in particular can be reached with playful explanations, such as lovingly animated figures that distinguish between good and bad pathogens/microorganisms and show them how to protect themselves from harmful ones.特別可以透過有趣的解釋來吸引兒童，例如用可愛的動畫人物來區分好與壞的病原體/微生物，並向他們展示如何保護自己免受有害病原體的侵害。

Augmented reality (AR) for hand hygiene training擴增實境（AR）用於手部衛生培訓

- Example範例: Nursing staff and doctors use AR glasses that show in real time which areas of the hands are often forgotten during hand disinfection. A visual representation (e.g. coloured markings) makes it immediately visible where microorganisms could still be present.護理人員和醫生使用AR眼鏡，即時顯示手部消毒過程中哪些區域容易被遺忘。視覺呈現（例如彩色標記）可以立即顯示哪些區域可能仍然存在微生物。

AI-supported simulations for infection prevention
人工智慧支援的感染預防模擬

- Example: Employees undergo virtual hygiene training with AI support. The software simulates various scenarios, e.g. an outbreak of multi-resistant pathogens. The participants have to make decisions (What protective measures are required now?) and the AI provides individualised feedback on the correct course of action.範例：員工在人工智慧的支援下接受虛擬衛生培訓。該軟體模擬各種場景，例如多重抗藥性病原體的爆發。參與者需要做出決策（例如現在需要採取哪些防護措施？），人工智慧會根據具體情況提供正確的行動方案。

Conclusion: Sustainable hygiene through modern training concepts
結論：透過現代培訓理念實現永續衛生

Hygiene must be explained in a simple and understandable way. Implementation must be practicable. We must be open to new approaches and adapt to the needs of different learning groups. Hygiene is far more than just a regulation. It is an attitude, a common goal that protects us all.衛生知識必須以簡單易懂的方式來解釋。實施必須切實可行。我們必須樂於接受新方法，並適應不同學習群體的需求。衛生不僅僅是一項規定。它是一種態度，一個保護我們所有人的共同目標。

For people to really embrace it, it must be communicated in a tangible and motivating way. 為了讓人們真正接受它，必須以一種實際的、激勵人心的方式來溝通。

Fig圖. 2: Make it naked: hands without jewellery赤裸裸：不戴首飾的手.

When employees are inspired by exciting training courses, when patients and visitors intuitively understand hygiene and when managers realise that infection prevention can be a competitive advantage, then it is not just behaviour that changes, but the entire culture of a facility.當員工受到令人興奮的培訓課程的啟發，當患者和訪客直觀地了解衛生知識，當管理人員意識到預防感染可以成為一種競爭優勢時，改變的不僅僅是行為，而是整個機構的文化。

Info from the Industry來自業界的訊息

The new Miele washer-disinfectors全新 Miele 清洗消毒機: ExpertLine sets new standards in instrument processing為儀器處理樹立了新標準

- Multilingual colour touch display simplifies workflows in medical practices
- Winner of the iF Design Award 2024
- Innovative technology for safe and efficient instrument reprocessing

All new cleaning and disinfection appliances from Miele are equipped with WiFi functionality and are network-enabled to connect to the Miele MOVE MedDent+ platform. Mobile devices can be used for cycle release and process documentation. This saves working time in a practice. (Photo: Miele)

Miele Professional is offering new, network-enabled cleaning and disinfection appliances for medical and dental practices under the name ExpertLine – tailored to the requirements of individual applications.

The illuminated wash cabinet of the 60 and 90 cm wide under-counter appliances makes loading easier and, together with a glass door (depending on the variant), turns the appliance into a real eye-catcher.

The colour touch display is intuitive to use. To support international practice teams: The language can be changed at any time with a simple click on the control display and batches can be released directly from the appliance screen. Alternatively, process documentation is available via the cloud-based platform Miele MOVE MedDent+, which provides practices with further important information on their infection control system.

Innovative technology such as frequency-controlled circulation pumps for generating different water pressures and spray arm speed monitoring ensures safe and efficient instrument processing. Two systems are available for subsequent drying.

Further information on this topic is available to users on www.miele-professional.com

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… Ines Liebig on online training and e-learning關於線上培訓和電子學習

Ines Liebig
Aseptio Hygieneberatung
衛生諮詢

***What challenges does the healthcare sector face*醫療保健產業面臨哪些挑戰?**

The healthcare sector is facing major challenges: Hygiene standards must be reliably adhered to, knowledge must be regularly updated and all employees – regardless of cultural background or previous experience – must be brought up to the same level of knowledge. In clinics, care facilities, medical centres and doctors' sur-geries, hygiene is not just a task, but the key to safety and trust for everyone involved.醫療保健產業正面臨重大挑戰：必須實際遵守衛生標準，定期更新相關知識，並提升所有員工（無論其文化背景或經驗如何）的知識水平。在診所、護理機構、醫療中心和醫生診所，衛生不僅僅是一項任務，也是所有相關人員安全和信任的關鍵。

***What contribution can online training in particular make in the coming years*線上培訓在未來幾年能做出哪些貢獻?**

In a world that is increasingly digital and globally networked, flexible and innovative training formats are becoming more and more important. E-learning of-fers enormous potential, particularly for start-ups that are developing pioneering solutions and for established companies, to meet the challenges of the coming years. Online training makes it possible to respond to the needs and understanding of generations Z and Y, which are characterised by digitalisation, mobility and sus-tainability. These target groups attach great importance to flexibility and direct, everyday benefits – aspects that online learning platforms optimally cover.在日益數位化和全球網路化的世界裡，靈活創新的培訓模式正變得日益重要。電子學習蘊含著巨大的潛力，尤其對那些正在開發開創性解決方案的新創公司和成熟企業而言，能夠幫助他們應對未來幾年的挑戰。線上培訓能夠滿足Z世代和Y世代的需求和理解，他們的特徵是數位化、行動化和永續性。這些目標群體非常重視靈活性和直接的日常效益— 而線上學習平台恰好能夠完美地滿足這些方面。

***To what extent is e-learning the better option for today's often international teams*對於現今的國際團隊來說，電子學習在多大程度上是更好的選擇?**

The HYGIENE COMPASS courses are available anywhere and at any time, without the need for integration into customer systems. A central feature of the platform are English specialised courses with integrated language modules. These innovative courses aim to support foreign specialists in the German healthcare sector. Participants can simultaneously expand their professional and language skills and graduate with two certificates – a professional certificate and a language certificate. This is an important step towards facilitating integration into everyday working life and tackling the shortage of skilled labour in a targeted manner.HYGIENE COMPASS 課程可隨時隨地使用，無需整合至客戶系統。該平台的核心特色是整合語言模組的英語專業課程。這些創新課程旨在為德國醫療保健行業的外籍專家提供支援。參與者可以同時擴展專業技能和語言技能，並在畢業時獲得兩項證書—專業證書和語言證書。這是促進外籍專家融入日常工作生活、有針對性地解決熟練勞動力短缺問題的重要一步。

E-learning concepts also take into account the different needs of the generations: Generation Z (up to 25 years) favours interactive, visual and playful content such as quizzes and learning games, Generation Y (25–40 years): Uses flexible and mobile learning formats that can be easily integrated into everyday working life, while Gen-eration X (40–55 years) and older employees require structured content and technical support in order to use digital platforms safely. And last but not least, e-learning is not only flexible, but also resource-efficient.電子學習概念也考慮到了不同世代的需求：Z世代（25歲以下）青睞互動性強、視覺化且趣味性強的內容，例如測驗和學習遊戲；Y世代（25-40歲）：使用靈活且移動化的學習形式，以便輕鬆融入日常工作；而X世代數字（40-55歲）及以上員工則需要結構化的內容和技術。最後，同樣重要的是，電子學習不僅靈活，而且資源高效。

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