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GRANDEVER BIOTECHNOLOGY CO., LTD.

20th April 2022

Professional Data Loggers for Medical Industry 應用於醫療行業的專業數據記錄器

Validation and Routine monitoring of steam sterilizer and washer-disinfector processes in hospitals 蒸汽滅菌器的驗證和日常監測醫院的清洗消毒流程

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Agenda
議程

1. Company Introduction 公司介紹
2. Where and when do you need to use data logger for medical industry 醫療行業何時何地需要使用數據記錄儀
3. Validation Loggers for Steam Sterilizers Process蒸汽滅菌器過程的驗證記錄器
4. Validation Loggers for Washer-Disinfectors Process清洗消毒器過程的驗證記錄器
5. Success Stories成功案例
6. Solutions for Other Devices其他設備的解決方案
7. Q&A問答

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1.Company Introduction
公司介紹

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Introduction介紹

Iven Kruse

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Introduction介紹

Helmut Schmidt

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Ebro Today

- Founded in Freiburg Germany in 1968
  1968 年在德國弗萊堡成立
- Focused on Medical, Pharma and Lab/ Industrial markets專注於醫療、製藥和實驗室/工業市場
- Global coverage with over 100 distributors worldwide全球覆蓋超過 100 家分銷商
- Xylem Analytics Germany Sales GmbH & Co. KG (XA Sales) since July 2016
  自 2016 年 7 月起加入Xylem Analytics Germany Sales GmbH & Co. KG (XA Sales)

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2. Who? Where? When? Why?
誰？在哪裡？什麼時候？為什麼？

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WHO needs the Professional Data Logger ? **誰**需要專業的數據記錄器?

Hospital 醫院

University Hospital
大學醫院

Medical Machine Manufacture
醫療機械製造廠

- Government 政府
- Validation company
  驗證公司
- Testing company
  檢測公司

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WHERE? 在哪裡？
Sterile Goods Cycle
無菌物品循環

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Operating Room Doctor手術室醫生

Preliminary disinfection
初步消毒

Logistics (receipt)
物流（接收）

RUMED (CSSD) Manager 醫療器械再處理單位(醫院中央無菌供應部)經理

Storage
貯存 (issue發布)

Washing 清洗

Packing包裝

Sterilization 滅菌

WHERE can you use our data logger?在哪裡您可以使用我們的數據記錄器?

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Process Validation & Routine monitoring for 流程驗證和例行監控

Washer-Disinfector 清洗消毒器

- Washer disinfector process 清洗消毒器消毒程序
- Washer disinfector for endoscopes processes用於內窺鏡過程的清洗消毒器
- Human waste container washer disinfector 人體廢物容器清洗消毒器

Steam Sterilizer 蒸汽滅菌器

- Electronic B&D test 電子式Bowie Dick蒸汽滲透真空測試
- Steam sterilizer processes 蒸汽滅菌器過程

Others 其他

- DAC processes 牙科高壓滅菌器/ Careclave 牙科器械的卡盤護理(Dental牙科)
- Plasma sterilizer processes (H2O2)電漿態過氧化氫滅菌流程
- Ethylene Oxide processes (EtO)環氧乙烷流程
- Formaldehyde processes (HCHO)甲醛流程

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WHY? 為什麼?

U.S.A 美國

- Biological Monitoring 生物的監測
- Chemical Monitoring 化學的監測

Guidelines: 準則

ANSI/AAMI ST79

European, Australia 歐洲, 澳洲

- Validation 驗證
- Physical Monitoring 物理的監測

Guidelines: 準則

EN 285
ISO 17665

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3. Validation for Steam Sterilizer Process蒸汽滅菌器流程驗證

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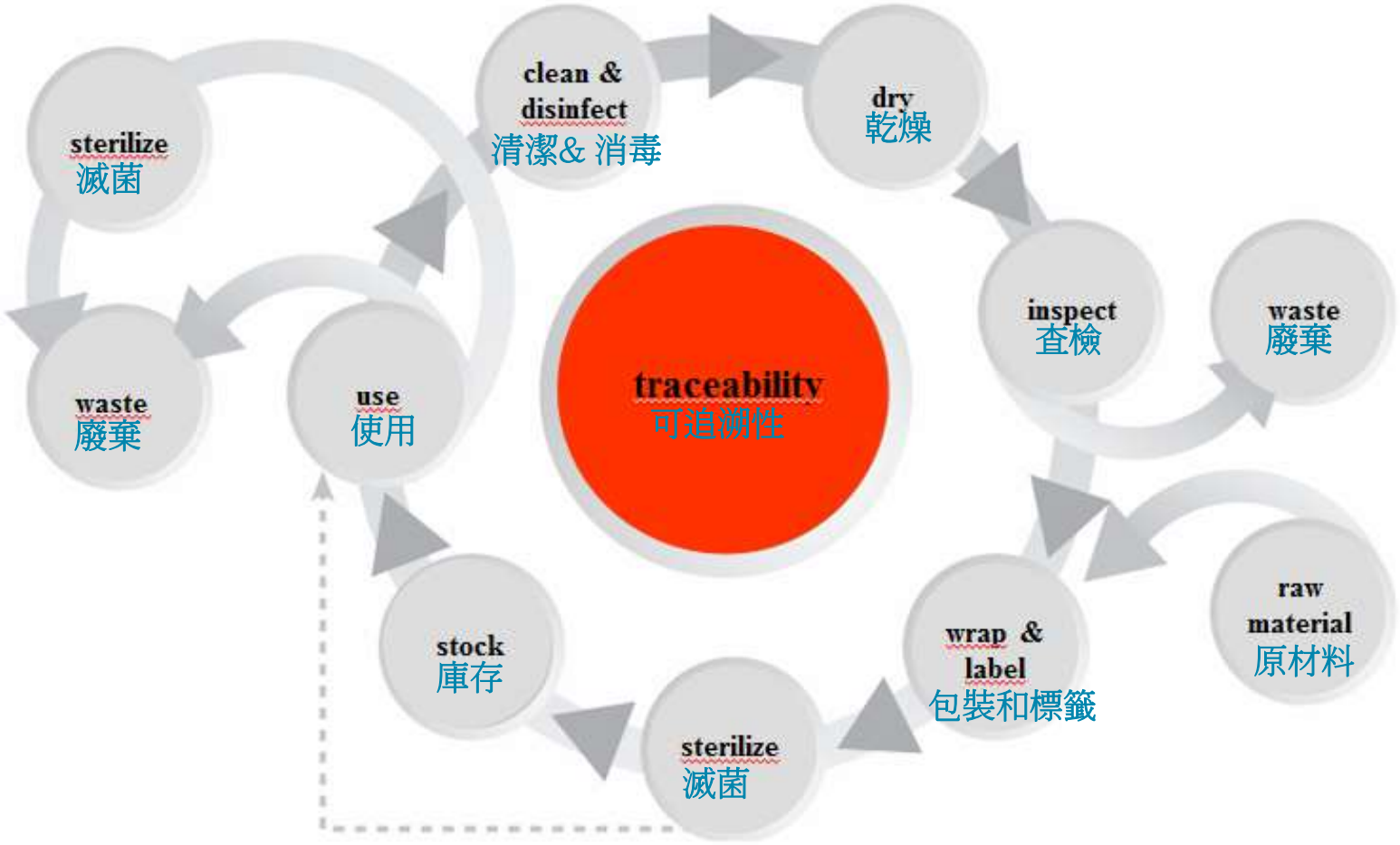
Reprocessing of medical devices 醫療器械再處理



High standards are required
需要高標準:

- Protection of patients保護患者
- Protection of employees保護職員
- Legal security法規保障
- Savings capacity儲積能力

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Definition „Validation“ 定義“驗證”

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What is a validation什麼是驗證?

Repeatable verification of the fact, that a process permanently reaches the required results.事實的重複驗證是一個永久達到需求結果的過程。

Where or when does a validation have to be performed必須在何時何地進行驗證?

In any case where the positive result of a process cannot be verified by simply one measurement.在任何情況下，僅通過一次測量無法驗證過程的正面結果。

Definition „Validation“ 定義“驗證”

- A validation includes the Installation Qualification (IQ), the Operation Qualification (OQ) and the Performance Qualification (PQ).驗證包括安裝認證 (IQ)、操作認證 (OQ) 和性能認證 (PQ)。

- A validation is clear prove for the fact, that procedures, processes, equipment, materials, process steps or systems actually lead to the expected results.驗證清楚地證明程序、過程、設備、材料、流程步驟或系統實際上引導預期結果的事實。

- The results are summarized and annotated in a validation report, which helps to work out and realize propositions for process optimization.結果在驗證報告中進行了總結和註釋，這有助於制定和實現流程優化的建議。

Legal basis and standards 法律依據和標準

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Standards and guidelines for steam sterilizer processes:蒸汽滅菌器流程的標準和指南：

DIN EN 285 large sterilizers大型滅菌器
EN 13060 small steam sterilizers小型蒸汽滅菌器 (< 60 liters公升)

EN ISO 17665 sterilization of products for health care – humid heat -requirements for the development, validation and control of the application of a sterilization process for medical products
醫療保健產品的滅菌 - 濕熱 - 醫療產品滅菌過程應用的開發、驗證和控制要求

EN ISO 11140-4 Routine control of steam sterilizers - alternative Bowie Dick Tests蒸汽滅菌器的常規控制 - 電子式Bowie Dick蒸汽滲透真空替代測試

Typical annual re-qualification is necessary 典型的年度重新認證是必要的(ISO 17665-2 part 12.4).

Installation Qualification安裝認證 (IQ)

1. Summary of the results 結果總結
2. Deviations and defects 偏差和缺失
3. General information 一般信息
4. Task formulation 任務制定
5. Identification of the device 設備識別
6. Check the documentation for completeness檢查文檔的完整性
7. Organisational preconditions for the validation驗證的組織前提條件
8. Installation control: environmental conditions, operating material, equipment, maintenance安裝控制：環境條件、操作材料、設備、維護
9. Description of the general state of the sterilizer滅菌器一般狀態說明
10. Company organisation – control of the quality assurance measures (trainings, daily operation, work instructions)公司組織-品質保證措施的控制（培訓、日常操作、工作指導）
11. Function 功能
12. Used measuring equipment 使用的測量設備

Prüfpunkte	Entsprechen: Ja / Nein	Bemerkung / Kommentar	Datum / Unterschrift
Allgemeine Angaben			
Allgemeine Angaben vollständig			
Aufgabenstellung vollständig			
Identifikation des Gerätes vollständig			
Prüfung der Dokumentation vollständig			
Organisatorische Vorbedingungen zur Validierung			
Installationskontrolle			
Umgebungsbedingungen			
Betriebsmittel			
Ausrüstung			
Allgemein			
Ausführung und Konstruktion			
Wartung			
Beschreibung des Allgemeinzustandes des Sterilisators			
Betriebsorganisation			
Arbeitsanweisungen			
Qualitätssicherung des täglichen Betriebs			
Schulungen			
Funktion			
Verwendete Messmittel			

Operation Qualification 操作認證(OQ)

1. General information 一般信息
2. Summary of the results and deviations / defects 結果和偏差/缺失的總結
3. Preconditions for the Operation Qualification 操作認證的前置條件
   - Collect medical products for the reference loading收集醫療產品以供參考裝載
   - Record medical products in packing lists在裝箱單中記錄醫療產品
   - Record the test configuration記錄測試配置
4. Checks 檢查
   - Conductivity of the feed water給水的電導率
   - Vacuum test真空測試
   - BD-test and/or Helix-test 抽真空BD 測試和/或 Helix 測試
   - Empty chamber profile空腔輪廓
   - Thermometric check with partial loading部分加載的測溫檢查
   - Thermometric check with full loading滿載溫度測量檢查

Performance Qualification 性能認證(PQ)

1. General information一般信息
2. Summary of the results and deviations / defects結果和偏差/缺失的總結
3. Preconditions for the Performance Qualification性能認證的前提條件
4. Checks 檢查
   - BD-test 蒸汽滲透真空測試
   - Three times product check 三次產品檢查
   - Proof of product compatibility產品兼容性證明
   - Proof of protection from recontamination防止再污染的證明
   - Proof of the identification ability識別能力證明
5. Determination of routine controls常規控制的量測

Validation of processes in steam sterilizers
蒸汽滅菌器中的驗證流程

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Thermometric check of the partial loading using dataloggers
使用數據記錄器對部分加載進行溫度測量

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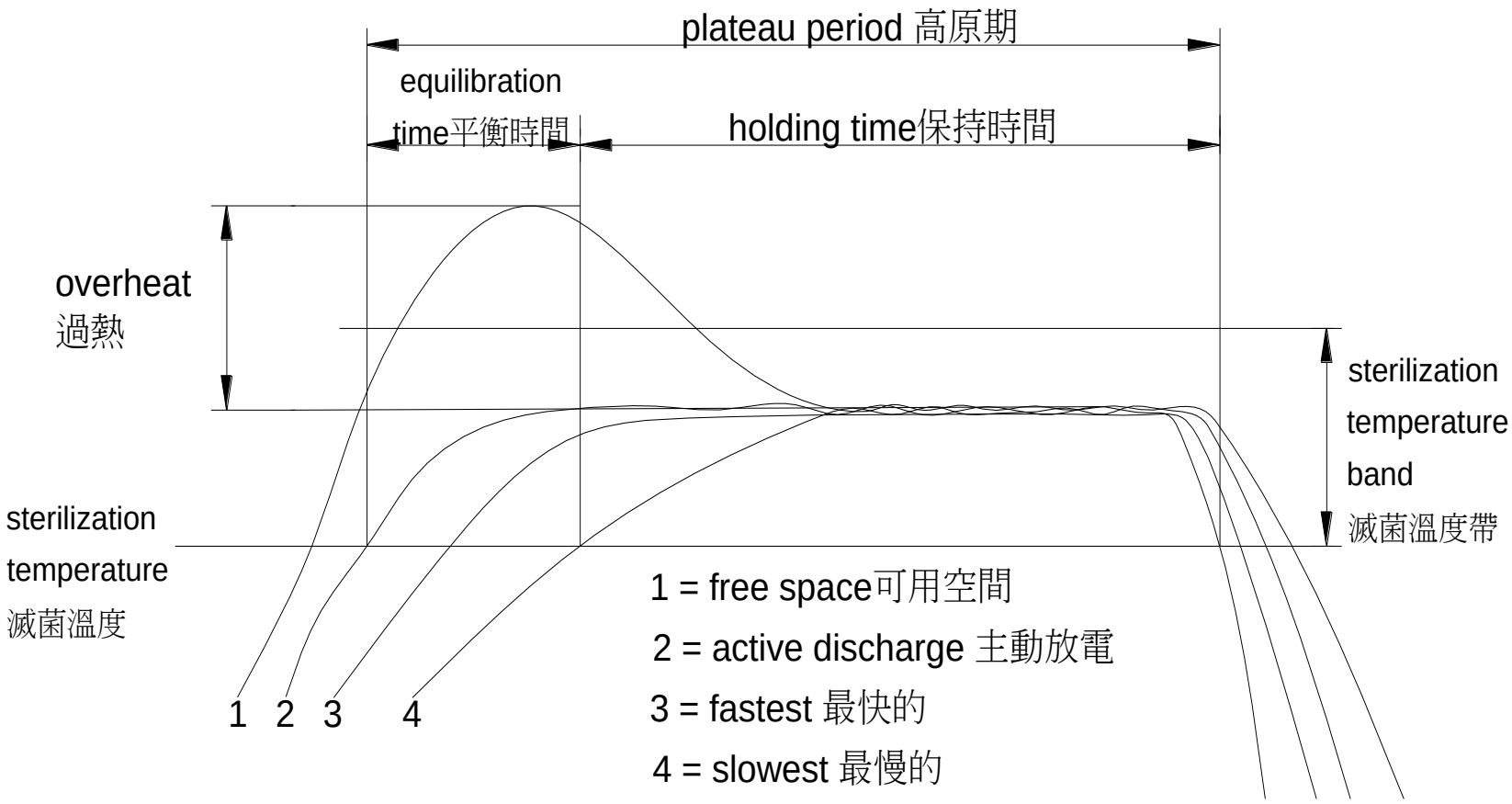
Validation of processes in steam sterilizers
蒸汽滅菌器中的驗證流程

Thermometric check of the full loading using dataloggers
使用數據記錄器對滿載進行溫度測量

Interpretation of the thermometric measurement result
溫度測量結果的解讀



Reaching the sterilization conditions達到滅菌條件

The existence of saturated steam in the usable area and within the loading can be considered as reached, if all temperatures measured in the usable area and within the loading during the hold time: 如果在保持時間內在可用區域和裝載內測量到的所有溫度，則可以認為在可用區域和裝載內存在**飽和蒸汽**：

- are not below the sterilization temperature **不低於**滅菌溫度
- are not more than 3K above the sterilization temperature 高於滅菌溫度不超過 **3K**
- do not diverge by more than 2° C 偏差不要超過 **2°C**
- equilibration time 15 s to 800 liter, 30 s for larger sterilizers 平衡時間 **15 秒**至 800 升，大型滅菌器為 **30 秒**
- minimum hold times 121 °C for 15 min; 126 °C for 10 min; 132° C for 3,5 min 134 °C for 3 min **最短**保持時間 121 °C 保持 15 分鐘； 126°C 10 分鐘； 132°C 3.5 分鐘 134°C 3 分鐘
- F_0-Value minimum 15 min F0 值至少 **15 分鐘**

The saturated steam temperature that is calculated with the measured pressure is to be considered as measured temperature. 以實測壓力計算的**飽和蒸汽**溫度作為實測溫度。

What if measuring values outside the tolerances
如果測量值超出公差範圍怎麼辦

What measures need to be taken in case the results **DO NOT** correspond to the specifications?如果結果不符合規格，需要採取哪些措施？

1. Check if the loading is correct? 檢查加載是否正確?
2. Positioning of the measuring sensors測量傳感器的定位
3. Repeated calibration of the measuring system測量系統的反復校準
4. Adjust process parameters by manufacturer or service company (e.g. confining / chamber pressure, pressure period)
   由製造商或服務公司調整流程參數（如限制/腔壓、壓力週期）
5. Alternative medical products? (materials, construction)替代醫療產品？（材料、結構）

Requirements for the measuring technology as per EN 285 / ISO 17665
根據 EN 285 / ISO 17665 對測量技術的要求

Temperature data logger溫度數據記錄器

- Temperature sensor made from platinum resistors Pt class A as per IEC 60751 or thermocouples class 1 as per IEC 60584-2,由符合 IEC 60751 的 **A 級鉑電阻器**或符合 IEC 60584-2 的 1 級熱電偶製成的溫度傳感器
- Diameter of the sensor ∅less than 2 mm 傳感器直徑小於2 mm
- Temperature measuring range 0 to 150 °C 溫 度 測 量 範 圍 0 至 1 5 0 °C
- Measuring interval 測量間隔 ≤ 2.5 s
- Resolution 解析度 0.1 K
- Accuracy of the temperature sensor at least 溫度傳感器的精度至少 0.5 K
- Accuracy of the temperature recording device 溫度記錄裝置的精度 ± 0.25 K
- Calibration of the temperature measuring technology according to manufacturer instructions; a temperature that lies within the sterilization temperature must be calibrated 根據製造商說明校準溫度測量技術；必須校準處於滅菌溫度範圍內的溫度 (DIN EN 285 Pt. 26.4.9)

Requirements for the measuring technology as per EN 285 / ISO 17665
根據 EN 285 / ISO 17665 對測量技術的要求

Pressure Data Logger壓力數據記錄器:

- Temperature-compensated pressure sensor 溫度補償壓力傳感器
- Measuring rate測量率 ≤1 s
- Measuring range of the pressure measuring device壓力測量裝置的測量範圍: 0 to 4 bar (0 to 400 kPa)
- Resolution解析度: 0.04 bar (4 kPa)
- Accuracy of the pressure measuring device ± 0.5 % of the measuring range, as long as the environment temperature is (20 ± 3°C)壓力測量裝置的精度為測量範圍的**± 0.5 %**，只要環境溫度為(20 ± 3°C)
- The device must have a valid certificate設備必須具有有效證書
- Calibration according to manufacturer instructions, traceable to a national standard (e.g. DKD), (DIN EN 285 Pt. 26.5)根據製造商說明進行校準，可溯源至國家標準（例如 DKD），（DIN EN 285 Pt. 26.5）

Validation report for sterilization processes

滅菌流程驗證報告

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Validering — Winlog.validation

Descr.: Tandhälsdan Tyresö 2017-11-30 Temp.prof.
30.11.2017 10:55:59 — Winlog.validation 3.71

Stockholm

General parameters

Device Stern Weber 17+	**SOP** -
Program Temp.profil	**Standard** DIN EN 13060
Creator Admin	**Charge number** -
Responsible Administrator	**Validated** 08.03.2018 15:07:16
Remark s/n: 17GP0028	

Loggers in process

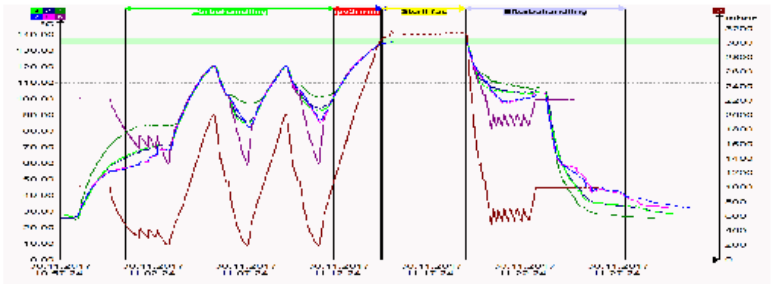
# 15177422	Calibration date 28.09.2017 09:48:00
# 15187298	Calibration date 28.09.2017 09:46:04
# 15187311	Calibration date 28.09.2017 09:47:36
# 15194093	Calibration date 28.09.2017 09:46:56
# 15202146	Calibration date 28.09.2017 09:46:39
# 15232080	Calibration date 28.09.2017 09:47:10

Overall result

Passed 已通過

Detailed results	Nominal	Actual
Pressure velocity increase (equilibration)		76.7 kPa/Min.
Pressure velocity decrease (drying)		296.2 kPa/Min.
Pressure velocity decrease (evacuation)		146.7 kPa/Min.
Max. variance	<= 2.00 K	0.24 K
Min. sterilization time	>= 180 sec.	270 sec.
Max. equilibration time	<= 15 sec.	5 sec.
Temperature range	134.00 - 138.00 °C	134.81 - 135.18 °C

Total measurement



Executed by — Verified by

Kwalfikacja procesowa — plastica

Descr.: 1st_16_11_2021-AC4-P1
05.01.2022 13:53:17 — Winlog.validation 3.71

Warsaw

General parameters

Device AC4	**SOP** -
Program P1	**Standard** -
Creator Admin	**Charge number** 3
Responsible Admin	**Validated** 13.04.2022 10:29:40

Loggers in process

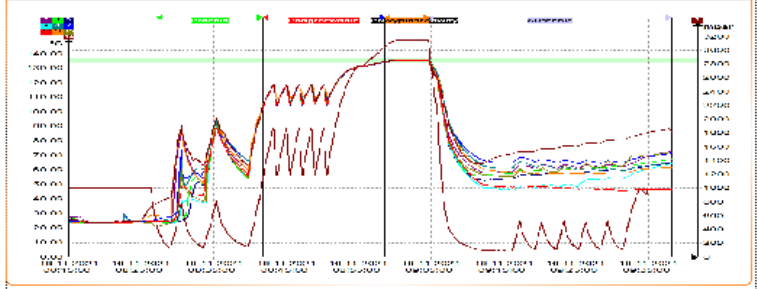
# 19705712	Calibration date 02.03.2021 08:04:25
# 19706213	Calibration date 13.01.2021 06:50:03
# 19706214	Calibration date 13.01.2021 06:49:09
# 19706215	Calibration date 13.01.2021 06:48:05
# 19706216	Calibration date 13.01.2021 06:47:48
# 19706217	Calibration date 13.01.2021 06:50:14

Overall result

Passed 已通過

Detailed results	Nominal	Actual
Pressure velocity increase (equilibration)		23.1 kPa/Min.
Pressure velocity decrease (drying)		107.8 kPa/Min.
Pressure velocity decrease (evacuation)		192.7 kPa/Min.
Max. variance	<= 2.00 K	1.16 K
Min. sterilization time	>= 330 sec.	357 sec.
Max. equilibration time	<= 15 sec.	6 sec.
Temperature range	134.00 - 137.00 °C	134.01 - 135.87 °C

Total measurement



Executed by Administrator — Verified by

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What is Bowie Dick Test?什麼是Bowie Dick蒸汽滲透真空測試?

To check if the air removal and steam penetration are successful
檢查排氣和蒸汽滲透是否成功

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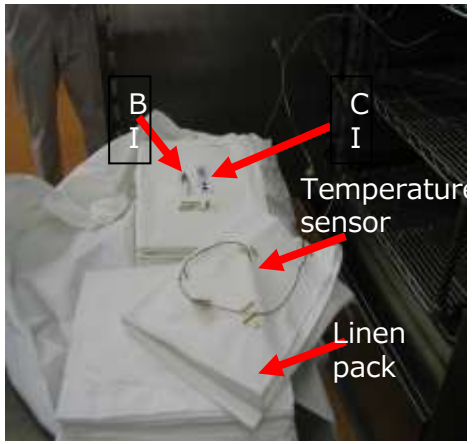
Original Test Pack原始測試包



Alternative BD Test 替代BD測試–
Electronic Bowie-Dick Test
電子式Bowie Dick蒸汽滲透真空測試

Alternative BD Test 替代BD測試–
Chemical Indicator化學指示劑

Alternative BD Test 替代BD測試–
Chemical Indicator化學指示劑

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Definition „Routine Control“ Daily Bowie Dick Test
定義“常規控制”每日鮑伊迪克測試

- **Routine control** is the periodical verification to check if the operating performance of the washer-disinfector or sterilizer meets the limit values that were defined during validation.例行控制是定期驗證，以檢查清洗消毒器或滅菌器的操作性能是否滿足驗證期間定義的限值。

Electronic Bowie & Dick Test 鮑伊迪克測試EBI 16

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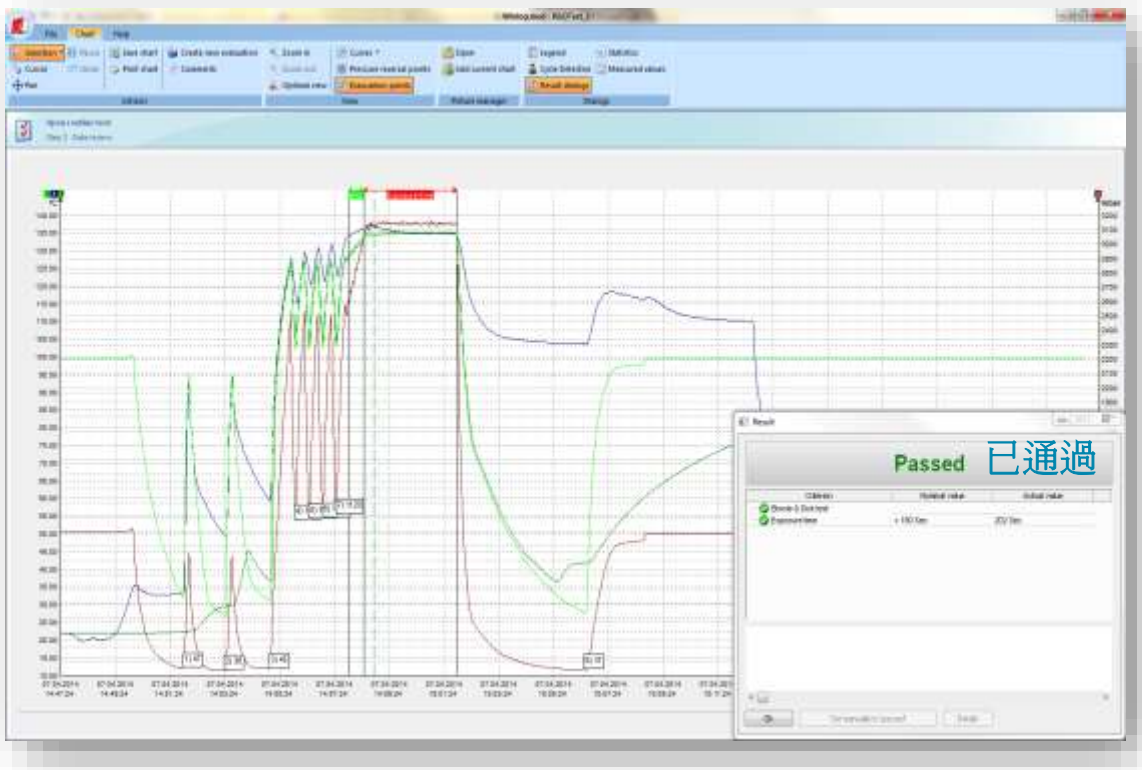
- Electronic BD test according to EN 285 / ISO 17665
  根據 EN 285 / ISO 17665 進行電子 BD 測試
- Air removal steam penetration test to verify the quality of sterilization除氣蒸汽滲透測試，驗證滅菌質量



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April 2022

4. Validation for Washer-Disinfector Process清洗消毒器流程的驗證

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Washer disinfectors - Validation
清洗消毒器 - 驗證

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Legal Background法規背景

- EN ISO 15883
  routine monitoring and validation of washer disinfectors清洗消毒器的常規監測和驗證

- EN ISO 15883-1:
  General requirements, definitions and verifications一般要求、定義和驗證
- EN ISO 15883-2:
  Requirements and checks for washer-disinfector devices with thermal disinfection for surgical instruments, anaesthesia instruments etc.對手術器械、麻醉器械等進行熱消毒的清洗消毒裝置的要求和檢查。
- EN ISO 15883-3:
  Requirements and checks for washer-disinfector devices with thermal disinfection for containers for human excretions
  人體排泄物容器熱消毒清洗消毒裝置的要求和檢查
- EN ISO 15883-4:
  Requirements and checks for washer-disinfector devices with chemical disinfection for thermolabile endoscopes對耐熱內窺鏡進行化學消毒的清洗消毒裝置的要求和檢查

  - WFHSS Guideline No. 02: Check List for Procurement of Medical Devices pursuant to EN ISO 17664:2004
    WFHSS 指南第 02 號：根據 EN ISO 17664:2004 採購醫療器械的清單

Washer disinfectors - Validation

清洗消毒器 - 驗證

Influences to the automatic cleaning and disinfection
對自動清洗消毒的影響

1. Washer disinfector device清洗消毒裝置:

   - Cleaning programs清潔程序
   - Disinfection programs消毒計劃
   - Rinse water circulation沖洗水循環

2. Loading裝載:

   - Arrangement towards the rinsing mechanics對沖洗機制的安排
   - Rinsing dead zones沖洗死區
   - Hollow spaces空洞空間

Washer disinfectors - Validation
清洗消毒器 - 驗證

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Influences to the automatic cleaning and disinfection
對自動清洗消毒的影響

3. Equipment設備:

- Water 水
- Steam 蒸汽
- Compressed air壓縮的空氣
- Energy supply 能源供應

4. Process Chemicals:流程化學品

- Detergents洗滌劑
- Disinfectants消毒劑
- Neutralization agents中和劑
- Rinsing agents沖洗劑

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Washer disinfectors - Validation
清洗消毒器 - 驗證

Influences to the automatic cleaning and disinfection
對自動清洗消毒的影響

5. Instrument Design儀器設計:

- Materials材料
- Joints連接處
- Hollow spaces空洞空間

6. Load Carrier 裝載載體:

- Rotating Arms旋轉臂
- Instrument holders儀器支撐
- Spray nozzles噴嘴

Washer disinfectors - Validation
清洗消毒器 - 驗證

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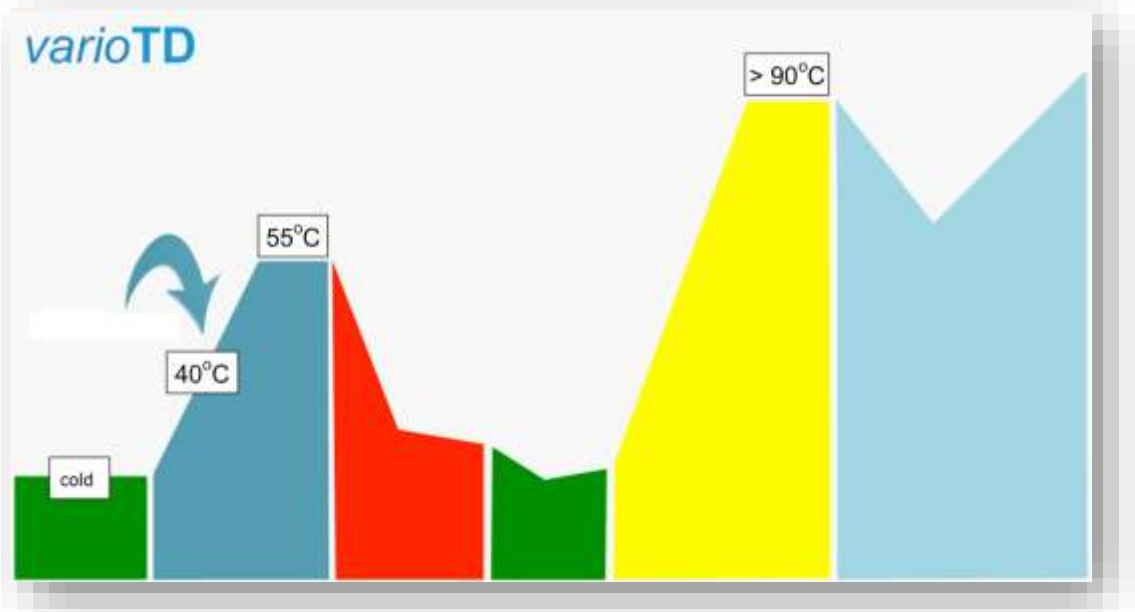
What is essential for the validation 驗證的必要條件是什麼?

- Temperature increase and hold time during the cleaning step and thermal disinfection 清潔步驟和熱消毒過程中的溫度升高和保持時間
- Pressure changes 壓力變化
- pH value 酸鹼度值
- Conductivity effect of the demineralized water軟化水的電導度效應
- Conductivity last rinsing water before draining排水前最後沖洗水的電導度



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Washer disinfectors - Validation
清洗消毒器 - 驗證

The validation consists of 驗證包括 :

- Installation Qualification 安裝認證 IQ
- Operation Qualification 操作認證 OQ
- Performance Qualification 性能認證 PQ

Washer disinfectors - Validation
清洗消毒器 - 驗證

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Installation Qualification 安裝認證 IQ

The Installation Qualification confirms that 安裝認證確認

- The WD and all ist accessories have been delivered properly and the installation has been performed professionally. WD 和所有ist 附件均已正確交付，並且安裝已專業完成。

- The connection to the matching supplies, water, power supply and process chemicals dosing pump system have also been completed perfectly.與配套供應、水、電力供應和流程化學品計量泵系統的連接也已完美完成。

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Washer disinfectors - Validation
清洗消毒器 - 驗證

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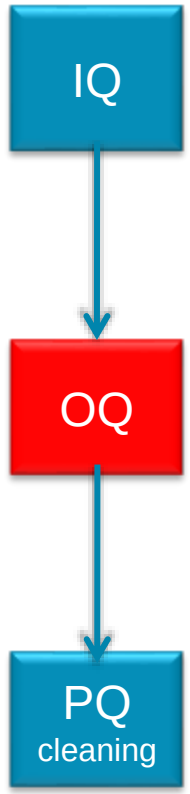
Operation Qualification 操作認證OQ

The Operation Qualification confirms that
操作認證確認

The complete WD unit and all the supplies are in accordance with the manufacturers requests and match the demands laid down in the DIN EN ISO 15883.

完整的WD裝置和所有供應品均符合製造商的要求，並符合DIN EN ISO 15883 中規定的要求。



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Washer disinfectors - Validation
清洗消毒器 - 驗證

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Cleaning and Disinfection Performance 清潔消毒性能

Checking the cleaning performance is done in two steps which can be combined, if necessary: 檢查清潔性能分兩個步驟進行，如有必要，可以合併：

1. Test instruments (test body) with defined test soiling具有定義測試污染的測試儀器（測試體）

2. Typical instruments, contaminated by use典型儀器，因使用而污染

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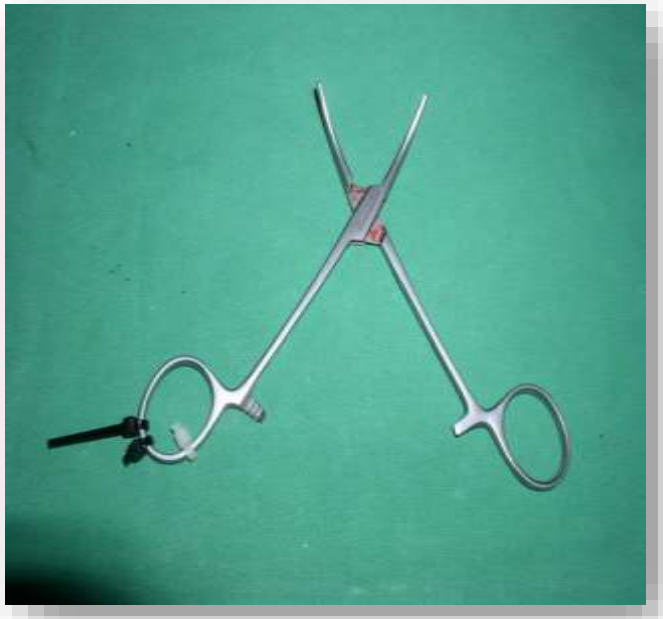
Washer disinfectors - Validation
清洗消毒器 - 驗證

Test instrument clamp according to Crile
with 0.1mg heparinised sheep blood with Protamine sulfate
根據 Crile 以0.1mg 肝素化羊血和硫酸魚精蛋白測試儀器夾具



Washer disinfectors - Validation
清洗消毒器 - 驗證

Test body and reference loading
with contaminated, general instruments
以使用受污染的通用儀器測試體和參考裝載

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清洗消毒器 - 驗證

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Step步驟 1 - Check optical cleanliness 檢查光學清潔度

The test instruments
(clamps according to Crile)
as well as the marked
contaminated instruments
are checked
regarding optical
cleanliness.
關於光學清潔度（根據 Crile
的夾具）測試儀器和標記受
污染儀器進行檢查
。

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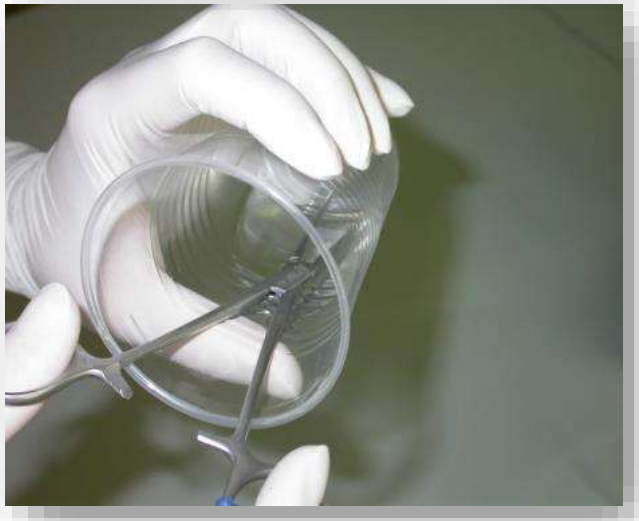
清洗消毒器 - 驗證

Step步驟 2 - Check for protein remains using the Biuret method 使用雙縮脲法檢查蛋白質殘留

- Remove the protein remains with SDS solution (sodium dodecyl sulfate; 1% in water) which is included in the test set or available in your own hospitals pharmacy使用 SDS 溶液（十二烷基硫酸鈉；1% 的水溶液）去除蛋白質殘留物，該溶液包含在測試集中或您自己的醫院藥房有供應



Washer disinfectors - Validation
清洗消毒器 - 驗證

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Biuret test set by Miele 德國美諾 Miele 雙縮脲測試儀

Biuret method with the swab procedure protect雙縮脲法與擦拭程序保護

IQ

OQ

PQ
cleaning

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Pressure measurement 壓力測量

Sufficient water pressure is precondition for the functioning of the spraying system用於噴灑系統的功能前提是水壓充足

- A pressure loss already occurs due to the blood proteins rinsed off and dissolved from the medical products.由於血液中的蛋白質被沖洗掉並從醫療產品溶解導致壓力損失。

- Pre-cleaning detergents can cause a major pressure drop.預清潔劑可能會導致一個主要的壓力下降。

- Pressure changes affect the rotation of the spray arms.壓力變化影響噴霧臂的旋轉。

- By using pressure loggers which record pressure and temperature in relation to time permanently during the complete process, these influences can be measured and evaluated.通過使用在整個過程中永久記錄與時間相關的壓力和溫度的壓力記錄器，可以測量和評估這些影響。

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Washer disinfectors - Validation
清洗消毒器 - 驗證

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An accident set should contain the following:
事故套裝應包含以下內容：

Description描述

- A simple possibility of batch control is offered by the following product compilation, which should not be missing in any RUMED. As part of an average concept, the use of data loggers can ensure standard-compliant monitoring and the RUMED can continue to operate.以下產品彙編提供了一種簡單的批次控制可能性，任何 RUMED 都不應缺少這些。作為一般概念的一部分，使用數據記錄器可以確保符合標準的監控，並且 RUMED 可以繼續運行。

Included in the set 包含在套裝中:

- 1x EBI 12-TP237 壓力記錄器
- 1x AL 101 矽膠保護盒
- 1x IF 150 啟始介面
- 1x Winlog.med 軟體
- 1x PHX 800 基礎版pH測試儀(聲音信號)
- 1x AL 128 Systainer case 工具箱
- 1x AL 1100 Foam insert 泡棉鑲嵌
- 1x TDS 3 基礎版電導度測試儀

Technical data

• Measurement range量測範圍	0ºC …+140ºC 1mbar… 4.000mbar
• Accuracy精準度:	± 0,3ºC ± 20mbar
• Resolution解析度	0,1°C 1mbar
• Battery電池	Lithium 3,6V, user exchangeable 鋰 3,6V，用戶可更換

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清洗消毒器 - 驗證

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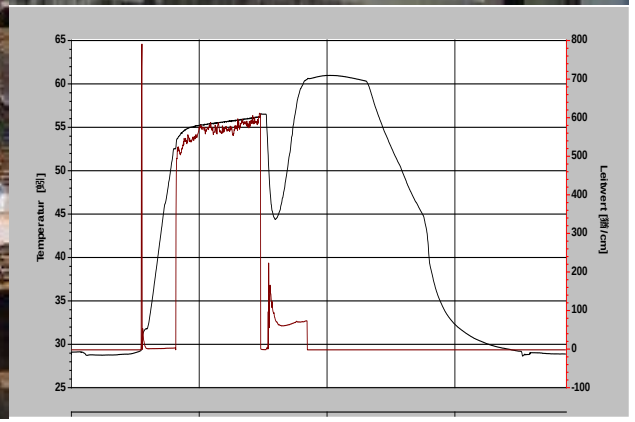
Performance Qualification 性能認證 PQ

Rinsing off all process chemicals / Verification by µS measurement

沖洗掉所有流程化學品/通過 µS 測量進行驗證



The washer-disinfector manufacturer needs to be informed by the manufacturer of the chemicals about all requirements for a safe handling, data of maximum permissible residual concentrations on the products and the proof procedure used for determining the process residues. 化學品製造商需要告知清洗消毒器製造商關於安全處理的所有要求、產品上最大允許殘留濃度的數據以及用於確定流程殘留物的證明程序。

It is important to measure the conductivity.
測量電導度很重要。

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Washer disinfectors - Validation
清洗消毒器 - 驗證

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Rinsing off all process chemicals / Verification by µS measurement 沖洗掉所有流程化學品/通過 µS 測量進行驗證

EBI 12-TC230 壓力記錄器plus外加
AL 132 Flow adapter流量適配器

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Washer disinfectors - Validation
清洗消毒器 - 驗證

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Disinfection performance消毒性能

The A_0 concept概念

The A_0-value of a disinfection procedure with moist heat is the mortification, indicated as time equivalent in seconds at a temperature of **80ºC** transferred to the product during the procedure, in relation to microorganisms with a Z-value of 10.濕熱消毒程序的 A0 值是以Z 值為 10 的微生物相關的在 **80ºC** 溫度下轉移到產品的時間，以秒為單位表示

The formula for the A-value calculation is A值計算公式為:

$$A_0 = \sum 10^{\frac{(T-80)}{z}} \cdot \Delta t$$

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Washer disinfectors - Validation
清洗消毒器 - 驗證

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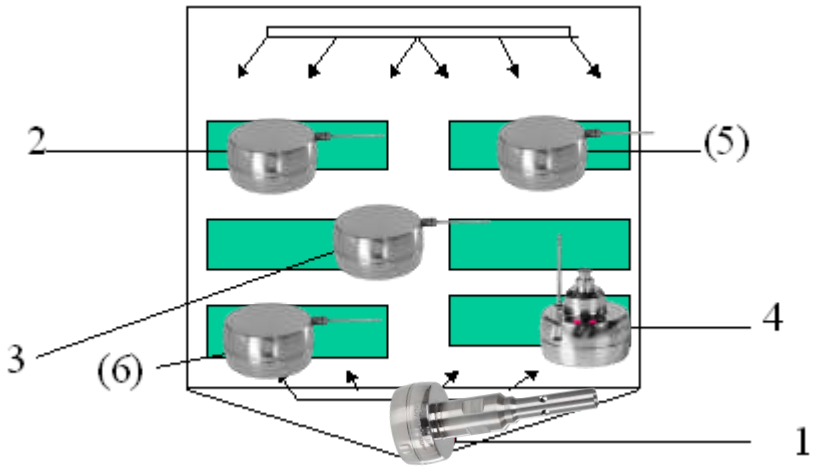
Thermal disinfection according to EN ISO 15883, 6.8.2
根據 EN ISO 15883, 6.8.2 進行熱消毒

Washer disinfector清洗消毒器



1…close to the sensor for automatic control靠近傳感器進行自動控制

2…place where the necessary temperature is reached the fastest最快達到所需溫度的地方

3…place where the necessary temperature is reached the slowest達到所需溫度最慢的地方

4,5,6…reference probes for the chamber temperature腔室溫度參考探頭

It is recommended to check 2 cycles with 6 sensors or 3 cycles with 4 sensors for every loading. **The use of biological indicators instead of dataloggers is not acceptable.** (ISO15883)建議每次裝載檢查 2 個循環（6 個傳感器）或 3 個循環（4 個傳感器）。使用生物指示劑代替數據記錄器是不可接受的。 (ISO15883)

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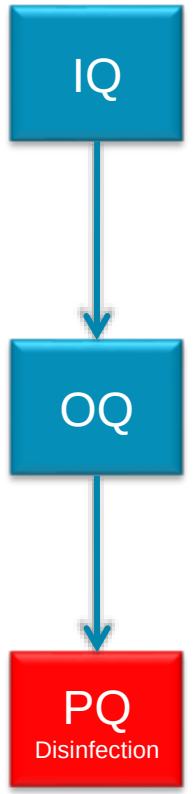
Washer disinfectors - Validation
清洗消毒器 - 驗證

A_0-values for a series of time-temperature relations
一系列時間-溫度關係的 A0 值:

Holding time保持時間		Temperature溫度	A_0-value值
min	s	°C	
1	–	80	60
–	6	90	60
10	–	80	600
100	–	70	600
1	–	90	600
1	–	93	1 200



Most European countries use A0 value of 3000.
大多數歐洲國家使用 3000 的 A0 值。

How often should people perform routine monitoring?
人們應該多久進行一次例行監測?

The frequency of the routine control is the responsibility of the operator例行控制的頻率由操作員負責。.

Washer-disinfectors with temperature documentation: Actual value with separate sensors / control-independent recording帶有溫度記錄的清洗消毒器：帶有單獨傳感器的實際值 /獨立於控制的記錄	**annually**每年
Washer-disinfector with temperature documentation: Actual value with separate sensors / control-dependent recording帶有溫度記錄的清洗消毒器：帶有單獨傳感器的實際值 /依賴於控制的記錄	**every 6 months**每6個月
Washer-disinfector with temperature documentation: Actual value without separate sensors帶有溫度記錄的清洗消毒器：沒有單獨傳感器的實際值	**every 3 months**每3個月
Washer-disinfector without temperature documentation or with nominal value display only沒有溫度記錄或僅顯示公稱值的清洗消毒器	**daily**每日

Washer disinfectors - Validation
清洗消毒器 - 驗證

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Suitable temperature and pressure logger合適的溫度和壓力記錄器

EBI 12 temperature logger with 1.5 mm flex probes radial and axial

EBI 12 溫度記錄器
具備 1.5 mm 柔性探頭
徑向和軸向

EBI 11 temperature logger with 1.5 mm flex probes EBI 11 溫度記錄器具備1.5 mm 柔性探頭

EBI 12 pressure logger with 2 mm rigid probe with luerlock (diameter 1.95 mm)
EBI 12 壓力記錄器具備魯爾鎖 2 mm 剛性探頭（直徑 1.95 mm）

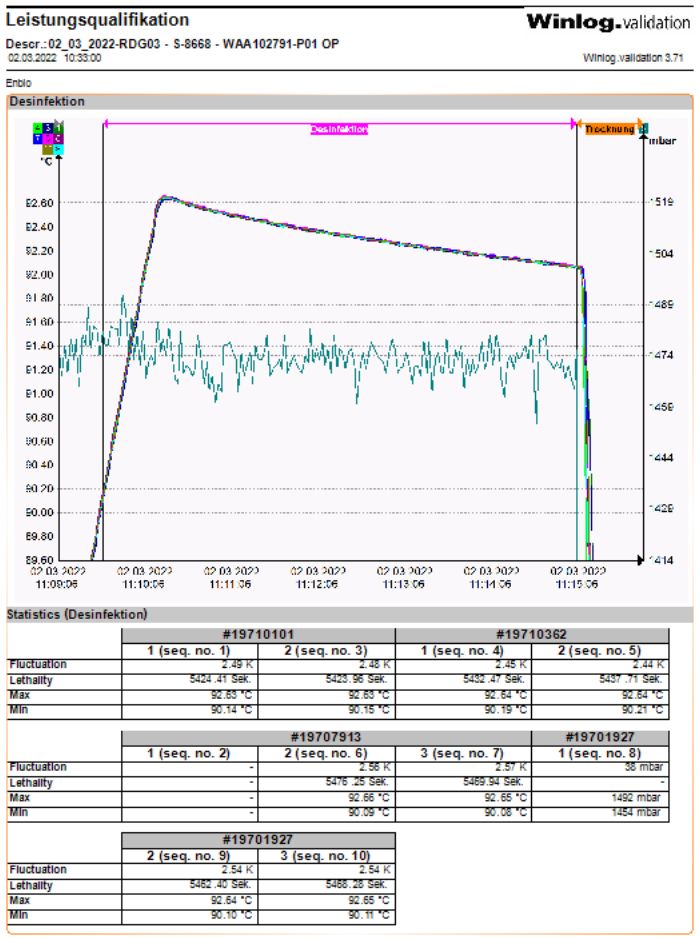
EBI 12 pressure logger with 1.5 mm flex probe with luerlock
EBI 12 壓力記錄器具備 1.5 mm 柔性探頭，具備魯爾鎖

EBI 11 temperature logger with 2 mm rigid probes (diameter 1.95 mm)
EBI 11 溫度記錄器具備 帶 2 mm 剛性探頭
（直徑 1.95 毫米）

EBI 11 pressure logger with luerlock and without luerlock
EBI 11 壓力記錄器具備或不具備魯爾鎖

Washer disinfectors - Validation

清洗消毒器 - 驗證



Leistungsqualifikation

Winlog.validation

Descr.:02_03_2022-RDG03 - S-8668 - WAA102791-P01 OP

02.03.2022 10:33:00

Winlog.validation 3.71

Enbio

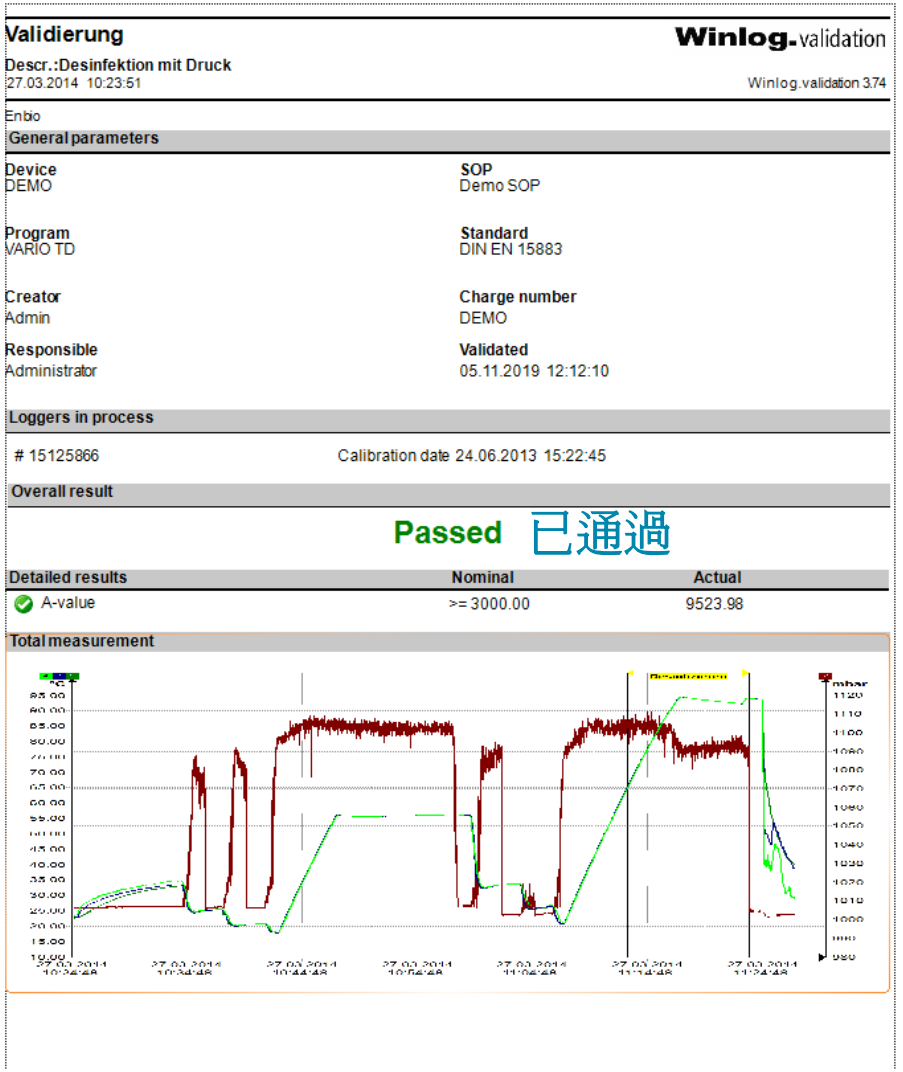
Desinfektion

Statistics (Desinfektion)

	#19710101		#19710362	
	1 (seq. no. 1)	2 (seq. no. 3)	1 (seq. no. 4)	2 (seq. no. 5)
Fluctuation	2.49 K	2.48 K	2.45 K	2.44 K
Lethality	5424.41 Sek.	5423.96 Sek.	5432.47 Sek.	5437.71 Sek.
Max	92.68 °C	92.68 °C	92.64 °C	92.64 °C
Min	90.14 °C	90.15 °C	90.19 °C	90.21 °C

	#19707913			#19701927
	1 (seq. no. 2)	2 (seq. no. 6)	3 (seq. no. 7)	1 (seq. no. 8)
Fluctuation	-	2.56 K	2.57 K	36 mbar
Lethality	-	5476.25 Sek.	5469.94 Sek.	-
Max	-	92.66 °C	92.65 °C	1492 mbar
Min	-	90.09 °C	90.08 °C	1454 mbar

	#19701927	
	2 (seq. no. 9)	3 (seq. no. 10)
Fluctuation	2.54 K	2.54 K
Lethality	5482.40 Sek.	5488.28 Sek.
Max	92.64 °C	92.65 °C
Min	90.10 °C	90.11 °C



Validierung

Winlog.validation

Descr.:Desinfektion mit Druck

27.03.2014 10:23:51

Winlog.validation 3.74

Enbio

General parameters

Device DEMO	SOP Demo SOP
Program VARIO TD	Standard DIN EN 15883
Creator Admin	Charge number DEMO
Responsible Administrator	Validated 05.11.2019 12:12:10

Loggers in process

15125866 Calibration date 24.06.2013 15:22:45

Overall result

Passed 已通過

Detailed results	Nominal	Actual
A-value	>= 3000.00	9523.98

Total measurement

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xylem
Let's Solve Water

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5. Success Stories
成功的案例

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Validation References -- Manufacturers and Importers

驗證參考-製造商和進口商

Worldwide contracts全球合約:

MELAG – for last two decades在過去的二十年裡

GETINGE

Miele - since自從 2002

Success in Asia在亞洲取得成功:

Sirona Dentsply, Australia New Zealand澳洲 紐西蘭

BELIMED

GETINGE Healthcare醫療保健, Australia澳洲

Miele

MMM, various countries各國

Big Hospitals – In-house validation engineers 大醫院—內部驗證工程師 SL 3111 and EBI 16

Catharina Ziekenhuis, NL荷蘭 醫院

Covering an area of 800 square metres佔地面積800平方米,

- 5 large chamber disinfectors 5 個大腔室消毒器
- 1 large chamber system for cleaning and disinfection 1 個用於清潔和消毒的大腔室系統
- 5 large sterilizers from Miele Professional
  5 個來自德國美諾 Miele Professional 的大型消毒器

Koç University hospital, TR 土耳其 大學醫院

Covering an area of 1,000 square metres佔地面積1000平方米,

- 12 large chamber disinfectors
  12個大腔消毒器,
- 12 large sterilizers from GETINGE 12 台 GETINGE 大型消毒器

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6. Solution for Other Devices
其他設備解決方案

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Plasma sterilizer process H_2O_2

電漿態過氧化氫滅菌流程

Legal background法律背景

- ISO/DIS 22441:2021-07
  - Sterilization of health care products – General requirements for characterization of vaporized hydrogen peroxide at low temperature保健產品的滅菌— 低溫汽化過氧化氫特性的一般要求
  - Validation and routine control of a sterilization process for medical devices醫療器械滅菌過程的驗證和常規控制

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Plasma sterilizer process H_2O_2 電漿態過氧化氫滅菌流程

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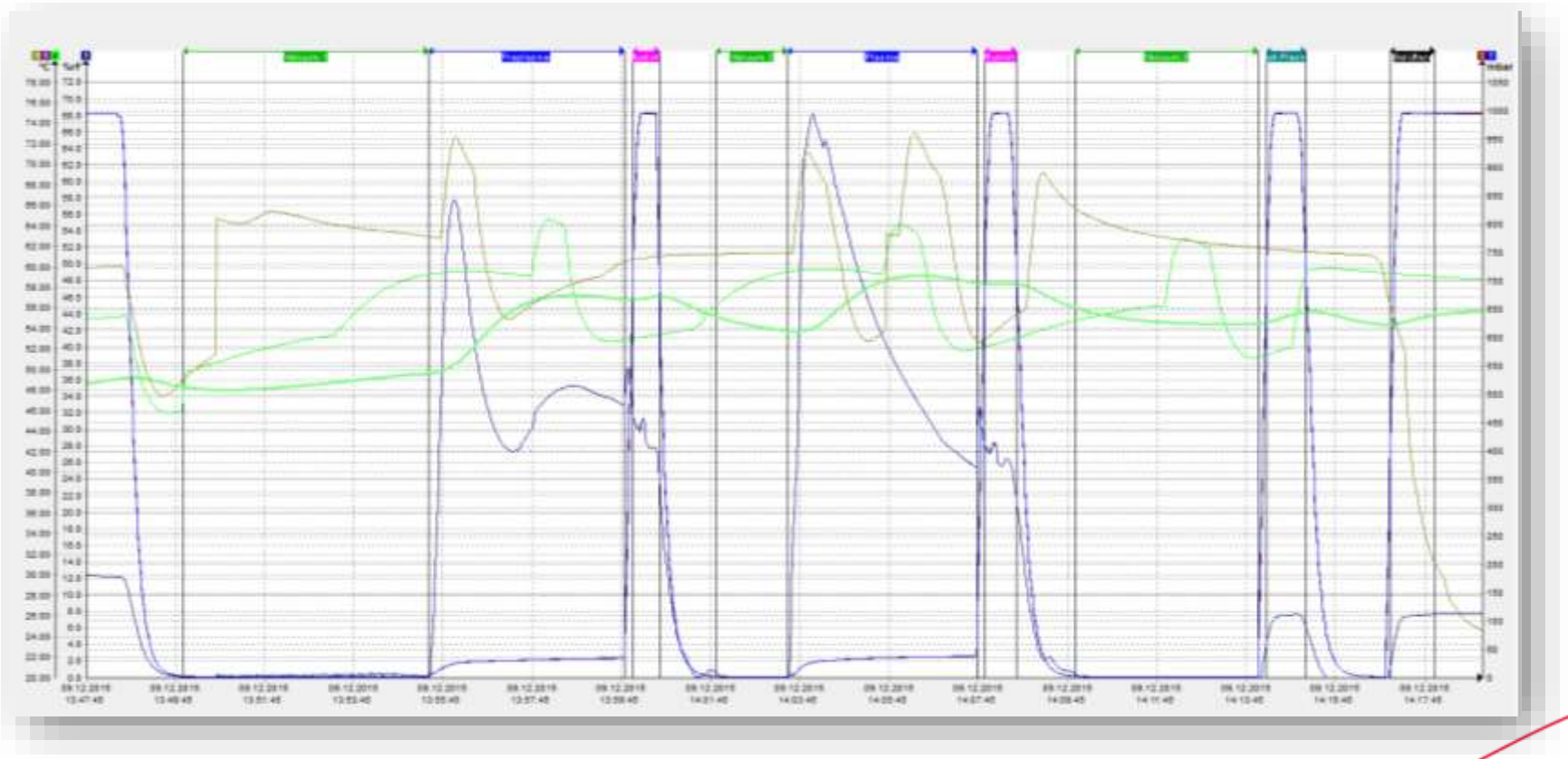
Example of a full plasma cycle完整的電漿態循環示例

1. Vacuum真空
2. Pre-plasma前電漿
3. Diffusion擴散
4. Vacuum真空
5. Plasma電漿
6. Diffusion擴散
7. Vacuum真空
8. Post-plasma後電漿
9. Ventilation通風



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Suitable temperature / pressure logger for measuring in Plasma sterilizer H_2O_2

在電漿態過氧化氫滅菌流程適合測量的溫度/壓力記錄器

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EBI 12-TPX9X

描述

- Data logger for gas sterilization processes
  氣體滅菌過程的數據記錄器
- The EBI 12-TP X9X pressure / temperature logger is developed for a precise measurement of pressure and temperature in low pressure sterilization processes. monitoring in H_2O_2 (plasma), formaldehyde sterilization processes EBI 12-TP X9X 壓力/溫度記錄儀專為精確測量低壓滅菌過程中的壓力和溫度而開發。
  H2O2（電漿態過氧化氫）、甲醛滅菌過程中的監測

技術數據

• Measurement range 測量範圍	0ºC …+85ºC 0,1mbar...1050mbar
• Accuracy精準度:	± 0,1ºC ± 0,2mbar (0,1…50mbar) ± 5% of measured value量測值 (50…100mbar) 1% FS (remaining range剩餘範圍)

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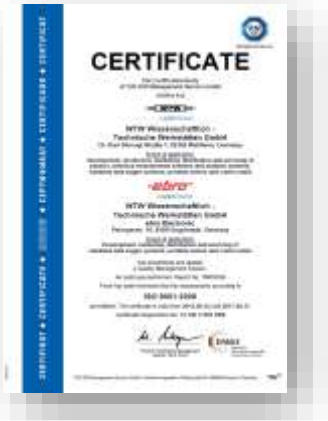
Advantage from the ebro data loggers and validation equipment
ebro 數據記錄器和驗證設備的優勢

- ✓ Data logger available for process validation according to ISO
  數據記錄器可用於根據 ISO 進行的流程驗證
- ✓ More than 20 years of experience with validation equipment
  超過 20 年的驗證設備經驗
- ✓ TÜV certified validation equipment TÜV 認證的驗證設備
- ✓ FDA 21 CFR Part 11 / IQ,OQ,PQ documents available
  可提供 FDA 21 CFR Part 11 / IQ、OQ、PQ 文件
- ✓ KompetenzCentrum in Ingolstadt 位在因戈施塔特的能力中心



- ✓ Member of the WFHSS(World Federation For Hospital Sterilisation Sciences
  世界醫院消毒科學聯合會)的會員
- ✓ Member of the hygiene magazine
  aseptica衛生雜誌無菌的會員
- ✓ Member of the DIN(Deutsches Institut für Normung德國標準化研究所)的會員

I WILL PRACTISE my profession with conscience and dignity and in accordance with good medical practice. 我將憑良心和尊嚴並按照良好的醫療實踐從事我的職業。

WMA DECLARATION OF GENEVA, 2018
WMA 日內瓦宣言 , 2018

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Let's Solve Water

大久生物科技股份有限公司
GRANDEVER BIOTECHNOLOGY CO., LTD.

April, 2022

Thank you謝謝您!

Welcome to send questions to
歡迎發送問題至:

GRANDEVER BIOTECHNOLOGY CO., LTD.
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11471 台北市內湖區新明路273巷6號1樓
1F., No.6, Ln. 273, Xinming Rd., Neihu Dist., Taipei City 11471, Taiwan (R.O.C.)
服務專線Tel ：(02)8792-3722
服務傳真Fax：(02)8792-3761
電子信箱Email：info@grandever-biotech.com.tw
公司網址Website: www.grandever-biotech.com.tw

Note: 此文件中文翻譯的部分若有進一步疑問，請參考原文或洽詢大久生物科技。

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