



# CERTIFICATE



This is to certify that the company



**Miele**

**Miele & Cie. KG**

Carl-Miele-Straße 29  
33332 Gütersloh  
Germany

with the organizational units/sites as listed in the annex  
has implemented and maintains a **Quality Management System**.

Scope of certification:

Design, development, production, distribution and service of appliances for cleaning and disinfection of medical devices, Distribution and service of appliances for sterilization of medical devices

**-AUS (a), CND, JPN, USA (a,b,c,d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	294819 MDSAP16
Certificate unique ID	1000202837
Effective date	2024-10-28
Expiry date	2027-10-27
Frankfurt am Main	2024-10-28



**DQS Medizinprodukte GmbH**

Sigrid Uhlemann  
Managing Director

Marc Goedecke  
Product Manager



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Tel. +49 (0) 69 95427-300, [info-med@dqs.de](mailto:info-med@dqs.de)

**DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.**

Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.

The validity of the certification can only be verified by the QR-code.



**Annex to certificate**  
**Certificate registration No.: 294819 MDSAP16**  
**Certificate unique ID: 1000202837**  
**Effective date: 2024-10-28**

## **Miele & Cie. KG**

Carl-Miele-Straße 29  
33332 Gütersloh  
Germany

### **Audited site**

**297112**

**Miele & Cie. KG**  
Carl-Miele-Straße 29  
33332 Gütersloh  
Germany

### **REPs FEI No.: site scope and country-specific requirements**

Distribution and service of appliances for  
cleaning and disinfection of medical devices.  
**AUS (a), CND, JPN, USA (a,b,c,d)**  
**REPs FEI No.: F002435**

**463747**

**Miele & Cie. KG**  
Mielestraße 2  
33611 Bielefeld  
Germany

Design, development and production of  
appliances for cleaning and disinfection of  
medical devices.  
**AUS (a), CND, JPN, USA (a,b,c,d)**  
**REPs FEI No.: F002435**



**Annex to certificate**  
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### **Full references of country-specific requirements of MDSAP participating Regulatory Authorities**

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821