EU Quality Management Certificate

This is to certify that the company

Miele & Cie. KG

Carl-Miele-Straße 29
33332 Gütersloh
Germany

SRN: DE-MF-000005768

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	294819 MDR2017Q
Certificate ID	1000169515
Effective date	2024-05-23
Expiry date	2026-11-03
Frankfurt am Main,	2024-05-23

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005768
Certificate ID: 1000169515

Device categories and variants covered by this certificate:

Device category:	**MDA 0317/A - Active non-implantable devices for cleaning and disinfection**
Product name:	PG 8562, PG 8581, PG 8582, PG 8582 CD, PG 8591, PG 8592, RID-100, RID-200
Risk classification:	IIb
Basic-UDI-DI:	4002515GG05MM
Intended purpose:	Reprocessable medical devices can be cleaned, rinsed, disinfected and dried in these Miele washer-disinfectors. These devices can be used in healthcare facilities such as practices, dental practices, hospitals, ambulatory surgical centers or veterinary facilities, depending of the type.

Device category:	**MDA 0317/A - Active non-implantable devices for cleaning and disinfection**
Product name:	ETD PAA Basic, ETD PAA Premium, ETD GA Premium, ETD GA Basic
Risk classification:	IIb
Basic-UDI-DI:	4002515ETD6D
Intended purpose:	The ETD is an endoscope washer-disinfector intended for automatic reprocessing for compatible flexible endoscopes. The reprocessing cycles consists of cleaning, rinsing, disinfection and optional dehumidifying.

Examinations and tests performed:
294819_A207836MED_01 dated 2021-07-30
420_12d_Bericht_Produktprüfung_Miele_K-Serie_korr dated 19.03.2021
294819_A211325MED_01 dated 13.01.2023

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2021-11-04	170775965	Extension Olympus ETD to the models ETD PAA Basic, ETD PAA Premium, ETD GA Premium, ETD GA Basic
02	2023-01-19	170782537	New certificate template