EU Technical Documentation Assessment Certificate

This is to certify that the company

Miele & Cie. KG

Carl-Miele-Straße 29
33332 Gütersloh
Germany

SRN: DE-MF-000005768

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

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

For placing medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	294819 MDR2017B
Certificate ID	170782538
Effective date	2023-01-19
Expiry date	2026-11-03
Frankfurt am Main,	2023-01-19

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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(active medical devices)

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Head of Certification Body
(non-active medical devices)

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005768
Certificate ID: 170782538

Device categories and variants covered by this certificate:

Device category:	**Cleaning and disinfection device**
Product name:	AztD_neue_K-Serie
Models:	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:	**Cleaning and disinfection device**
Product name:	AztD_ETD
Models:	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:
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:
Products listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2021-11-04	170775971	Extension Olympus ETD to the models ETD PAA Basic, ETD PAA Premium, ETD GA Premium, ETD GA Basic