



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. Limitations to this certificate are listed in the Annex.

Certificate registration no. 294819 MDR2017Q

 Certificate ID
 170782537

 Effective date
 2023-01-19

 Expiry date
 2026-11-03

 Frankfurt am Main,
 2023-01-19



DQS Medizinprodukte GmbH

Sigrid Uhlemann Managing Director

Michael Bothe Head of Certification Body (active medical devices) Szymon Kurdyn Head of Certification Body

S. Kudyn

(non-active medical devices)



Michael Bothe



Annex to EU Quality Management Certificate SRN of Manufacturer: DE-MF-000005768 Certificate ID: 170782537

Device categories covered by this certificate:

Device category: Cleaning and disinfection device

Risk classification: IIb

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

Risk classification: IIk

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

Further conditions for or limitations to the validity of the certificate:

The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

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