



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company



Miele & Cie. KG

Carl-Miele-Straße 29
33332 Gütersloh
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Washer /Disinfector according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	294819 MR2
Certificate unique ID	170755583
Effective date	2019-10-30
Expiry date	2023-10-26
Frankfurt am Main	2019-10-30

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
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Miele & Cie. KG

Carl-Miele-Straße 29
33332 Gütersloh
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Brand

Miele

Device family

Washer / Disinfector

Device	Class
G 7823	IIb
G 7824	IIb
G 7825	IIb
G 7826	IIb
PG 8527	IIb
PG 8528	IIb
PG 8536	IIb
PG 8535	IIb
PG 8581	IIb
PG 8591	IIb
PG 8562	IIb
PG 8582	IIb
PG 8592	IIb
PG 8582 CD	IIb
PWD 8626	IIb
PWD 8628	IIb



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Miele & Cie. KG

Carl-Miele-Straße 29
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Brand
Steelco

Device family
Washer / Disinfector

Device	Class
PWD 8626	IIb
PWD 8628	IIb
DS 508	IIb
DS 508 X	IIb



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Miele & Cie. KG

Carl-Miele-Straße 29
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Brand
Olympus

Device family
Washer / Disinfector

Device	Class
Mini ETD 2	IIb
ETD 4	IIb



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Carl-Miele-Straße 29
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Brand
W&H

Device family
Washer / Disinfector

Device	Class
RID-100	IIb
RID-200	IIb