

Certificate

EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) of
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

BSI Group Deutschland GmbH

Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main
Germany

in its function as Notified Body (0535), that the manufacturer:

MELAG Medizintechnik oHG

Geneststraße 6-10
10829 Berlin
Germany

concerning the medical devices

Steam and dry heat sterilizers as well as washer-disinfectors

Class IIb

(products/variants specified in appendix)

fulfils the requirements according to Annex II (excluding section 4) Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the design, production and final inspection of the specified devices.

For the placing on the market of class III products an additional Annex II section 4 certificate is required.

The appendix is part of this certificate and contains 2 pages.

Report No.: SMO7717754

Certificate No.: CE 576004

ZLS Notified by
Zentralstelle der Länder
für Sicherheitstechnik
ZLS-NB-67/12

First Issue Date:
November 04, 2010.

Based on periodical surveillance
this certificate is valid until
November 03, 2015.

Current Issue Date: November 29, 2013

Wilfried Bebel

Certification Body

Translation

Appendix of EC-Certificate

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according to annex II (excluding section 4) of Medical Devices Directive 93/42/EEC

Certificate No.: CE 576004

Medical devices of the manufacturer:

MELAG Medizintechnik oHG

Geneststraße 6-10

10829 Berlin

Germany

Name of product	Variant	Item	UMDNS	Class
Steam sterilizer				
Premium-Plus-Class	Vacuklav 40 B+	10060	16-142	IIb
	Vacuklav 41 B+	10061		
	Vacuklav 43 B+	10063		
	Vacuklav 44 B+	10064		
Premium-Class	Vacuklav 40-B	10040	16-142	IIb
	Vacuklav 41-B	10041		
	Vacuklav 43-B	10043		
	Vacuklav 44-B	10044		
Profi-Class	Vacuklav 23 B+	10053	16-142	IIb
	Vacuklav 24 B+	10054		
	Vacuklav 24 BL+	10052		
	Vacuklav 30 B+	10050		
	Vacuklav 31 B+	10051		
S-Class	Euroklav 23 VS+	10056	16-142	IIb
	Euroklav 29 VS+	10057		
	Euroklav 23 S+	10055		

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Medical devices of the manufacturer:

MELAG Medizintechnik oHG

Geneststraße 6-10

10829 Berlin

Germany

Name of product	Variant	Item	UMDNS	Class
Steam sterilizer				
MELAtronic	MELAtronic 15 EN+	10615	16-142	IIb
	MELAtronic 17 EN	10517		
	MELAtronic 23 EN	10523		
Cliniklav / Cliniclave	Cliniklav 25	10025	16-142	IIb
	Cliniclave 45	10045		
		10047		
Vacuquick	Vacuquick 13-B	10013	16-142	IIb
	Vacuquick 14-B	10014		
MELAquick	MELAquick 12+	10012	16-142	IIb
	MELAquick 12+ p 50Hz	11012		
	MELAquick 12+ p 60Hz	12012		

Name of product	Variant	Item	UMDNS	Class
Dry heat sterilizer				
Sterilizer	Sterilizer 75	00075	13-739	IIb
	Sterilizer 205	00205		
	Sterilizer 255	00255		
Washer-Disinfector				
MELAtherm 10 DT	A	10020	11-278	IIb
	B	10021		