

Certificate

Quality-Assurance System

acc. to Directive 2014/68/EU

Certificate no.:

01 202 644/Q-18 B008

Name and address of the
manufacturer:

MELAG Medizintechnik oHG
Geneststr. 6-10
10829 Berlin
Germany

Herewith we certify that the above -mentioned manufacturer operates a quality system according to the European Directive 2014/68/EU. The manufacturer has the permission to affix the following CE marking to pressure equipment described and manufactured in accordance to the scope covered by this Quality-Assurance System:

CE 0035

Tested acc. to
Directive 2014/68/EU:

QA-System (Module D)
(the QA-Modules E1, E and D1 are covered by Module D)

Audit report no.:

644/Q-18 B008

Area of validity:

Production of sterilisers for medical purposes and safety valves, see annex to certificate

Manufacturing plant:

MELAG Medizintechnik oHG
Geneststr. 6-10
10829 Berlin
Germany

Valid until:

May 31, 2021

Cologne, May 31, 2018

i.V. Dipl.-Ing. Oliver Theisen



TÜV Rheinland Industrie Service GmbH
Notifizierte Stelle für Druckgeräte, Kennnummer: 0035
Am Grauen Stein, D-51105 Köln

E-008-D-Rev22

Appendix of certificate no. 01 202 620/Q/03 0412/009
Field of application for producer of pressure equipment with accredited QM-system; agreeable to DGR 97/23/EG – Module D

Producer		Manufacturing plant		Nationality	Date	Sheet-No	TÜV-Name /Stamp
Name: MELAG Medizintechnik oHG		MELAG Medizintechnik oHG			18.05.2015	1	TÜV Rheinland
Adresse: Geneststr. 6-10 10829 Berlin		Geneststr. 6-10 10829 Berlin			Rev.: 1	2	Industry service GmbH
Item	Product description	Used comprehensive body of legislation	Materials	Limitation of use	List of „modul B/B1“ Certificate („QS-Modul D/E“)	Comment	
1.	Chamber, Typ 31 K Vacuklav 30-B/31-B/30 B+/31 B+	AD2000	1.4571/1.4435	-1 / 3 bar	Ku071123 Rev.b		
2	Chamber, Typ 31 L Vacuklav 23-B/24-B/23 B+/24 B+	AD2000	1.4571/1.4435	-1 / 3 bar	Ku080216 Rev.b		
3	Chamber/Typ 25 Cilniklav 25	AD2000	1.4571	-1 / 2,45 bar	Ku021222 Rev.a		
4	Chamber Typ 15.2 MELAtronic 15	AD2000	1.4571 / 1.4301	3 bar	Ku021215 Rev.a		
5	Chamber Typ 17.2 MELAtronic 17 / 17 EN	AD2000	1.4571 / 1.4301	3 bar	Ku021216 Rev.a		
6	Chamber Typ 23.2 MELAtronic 23 / 23 EN	AD2000	1.4571 / 1.4301	-1 / 3 bar	Ku021217 Rev.a		
7	Chamber, Typ 23 K Euroklav 29-S/29V-S/29 VS+	AD2000	1.4571/1.4435	-1 / 3 bar	Ku021218 Rev.b		
8	Chamber, Typ 23 L Euroklav 23-S/23V-S/23 S+/23 VS+	AD2000	1.4571/1.4435	-1 / 3 bar	Ku021219 Rev.b		



Appendix of certificate no. 01 202 620/Q/03 0412/009

Field of application for producer of pressure equipment with accredited QM-system; agreeable to DGR 97/23/EG – Module D

Producer			Manufacturing plant		Nationality	Date	Sheet-No	TÜV-Name /Stamp
Name: MELAG Medizintechnik oHG			MELAG Medizintechnik oHG			18.05.2015	2	TÜV Rheinland
Adresse: Geneststr. 6-10 10829 Berlin			Geneststr. 6-10 10829 Berlin			Rev.: 1	of: 2	Industry service GmbH
Item	Product description	Used comprehensive body of legislation	Materials	Limitation of use	List of „modul B/B1“ Certificate (QS-Modul D/E“)	Comment		
9	Chamber, Ø250, L=600 (650) long Vacuklav 24 BL/24 BL+	AD2000	1.4571/1.4301	-1 / 3 bar	Ku080507			
10	Chamber Typ C45 Clinclave 45	DIN EN 13445	1.4571/1.4301	-1 / 2,7 bar	Ku120309			
11	Chamber Typ C45-D Clinclave 45-D	DIN EN 13445	1.4571/1.4301	-1 / 2,7 bar	Ku120310			
12	Chamber Typ C45-M Clinclave 45-M	DIN EN 13445	1.4571/1.4301	-1 / 2,7 bar	Ku120311			
13	Chamber Typ C45-MD Clinclave 45-MD	DIN EN 13445	1.4571/1.4301	-1 / 2,7 bar	Ku120312			
14	Chamber, Typ 15 EN MELATronic 15 EN+	AD 2000	1.4571 / 1.4301	3 ba	Ku 100616			
15	Chamber, compl. MELATronic 15 EN	AD 2000	1.4571 / 1.4301	3 bar	Ku 100615			
16	Chamber, Typ 30 D Vacuklar 40-B/41-B/40B+/41B+/44B+	AD 2000	1.4571 / 1.4301	-1 / 3,5 bar	Ku 100408			
17	Chamber, Typ 24 D Vacuklar 43-B/44-B/43B+/41B+/44B+	AD 2000	1.4571 / 1.4301	-1 / 3,5 bar	Ku 100409			

