MELAG
competence in hygiene

MELAG Medizintechnik | Geneststraße 6 – 10 | 10829 Berlin

To whom it may concern

MELAG Medizintechnik
GmbH & Co. KG

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06.05.2024

Manufacturer information letter on the further handling of MELAG's medical devices falling under 93/42/EEC Medical Device Directive after May 26, 2024

Dear Sir / Madam,

According to the (EU) 2017/745 regulation on medical devices (MDR), our 93/42/EEC Medical Device Directive (MDD) certificate HD 1082891-1 will expire May 26, 2024 and no new certificate will be issued. The validity of our MDD certificate has been extended by law (Regulation (EU) 2023/607), i.e. it remains valid beyond the end of the specified period of the MDD certificate until **December 31, 2028** in accordance with the amended MDR for the following products:

- Premium-Plus-Class (Vacuklav 40 B+, Vacuklav 41 B+, Vacuklav 43 B+ and Vacuklav 44 B+)
- Pro-Class (Vacuklav 23 B+, Vacuklav 24 B+, Vacuklav 24 BL+, Vacuklav 30 B+ and Vacuklav 31 B+)
- S-Class (Euroklav 23 S+, Euroklav 23 VS+ and Euroklav 29 VS+)
- MELAquick (MELAquick 12+ and MELAquick 12+ p)
- Cliniclave (Cliniclave 45, Cliniclave 45 M, Cliniclave 45 D and Cliniclave 45 MD)
- MELAtherm 10 (MELAtherm 10 DTA, MELAtherm 10 DTB, MELAtherm 10 Evolution DTA and MELAtherm 10 Evolution DTB)

The following products will be discontinued as MDD products on May 26, 2024:

- Careclave 618 (is transferred to the MDR and will therefore remain marketable after May 26, 2024)
- MELAtronic (MELAtronic 15 EN+ and MELAtronic 23 EN)

The extension letter and MDD certificate from the notified body as well as the manufacturer self-declaration are attached as an appendix to this letter.

Dr. Niklas Gebauer, CEO

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	MELAG Medizintechnik GmbH & Co. KG
Manufacturer address and contact details	Geneststr. 6-10, 10829 Berlin, Germany
Single Registration Number (SRN) (if available)	DE-MF-000006703

Authorised Representative name (if applicable)	NA
Authorised Representative address and contact details	NA
Single Registration Number (SRN) (if available)	NA

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH
Notified body number (if applicable)	0197
Directive Certificate number(s) to which this confirmation is made (if applicable)	HD 1082891-1

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26
End date of extended validity/transition period	See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made/submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or its/their substitute(s) and signed written agreement(s) will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.
- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name MELAG Medizintechnik GmbH & Co. KG

Location & Date Berlin, 26.03.2024

Signature, Print Name, Title

Dr. Matthias Liebetrau, PRRC

Contact Details (at least email) info@melag.de

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (The product group is highlighted in bold)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period according to (EU) 2023/607**
Premium-Plus-Class Vacuklav 40 B+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Premium-Plus-Class Vacuklav 41 B+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Premium-Plus-Class Vacuklav 43 B+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Premium-Plus-Class Vacuklav 44 B+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Pro-Class Vacuklav 23 B+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Pro-Class Vacuklav 24 B+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Pro-Class Vacuklav 24 BL+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Pro-Class Vacuklav 30 B+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Pro-Class Vacuklav 31 B+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
S-Class Euroklav 23 VS+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
S-Class Euroklav 23 S+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
S-Class Euroklav 29 VS+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31

Cliniclave Cliniclave 45	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Cliniclave Cliniclave 45 M	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Cliniclave Cliniclave 45 D	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
Cliniclave Cliniclave 45 MD	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
MELAquick MELAquick 12+	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
MELAquick MELAquick 12+ p	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
MELAtherm 10 MELAtherm 10 DTA	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
MELAtherm 10 MELAtherm 10 DTB	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
MELAtherm 10 MELAtherm 10 Evolution DTA	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31
MELAtherm 10 MELAtherm 10 Evolution DTB	HD 1082891-1	2024-05-26	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH, 0197	2028-12-31

EC Certificate

TÜVRheinland®

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 1082891-1

Manufacturer: MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

Products: Active devices for disinfection and sterilization

Product groups included:

- Careclave
- Cliniclave
- MELAtronic
- MELAquick
- MELAtherm 10
- Premium-Plus-Class
- Pro-Class
- S-Class

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3327953-90

Effective date: 2021-01-28

Expiry date: 2024-05-26

Issue date: 2021-01-28

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. A. Fechner
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 1082891-1

Manufacturer: MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Scope
/01	MELAG Medizintechnik GmbH & Co. KG Geneststr. 6-10 10829 Berlin Germany	Design/development and manufacture
/02	MELAG Medizintechnik GmbH & Co. KG Geneststr. 2 10829 Berlin Germany	Design/development and manufacture

Report No.: 3327953-90

Effective date: 2021-01-28

Expiry date: 2024-05-26

Issue date: 2021-01-28

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 29, 2024

Notified Body Confirmation Letter
Reference: MDR_Application 2024-04-05, Order number: #1160747

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany
SRN Number (if available): DE-MF-000006703

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
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Germany

Headquarter

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90431 Nuremberg

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Fax +49 911 655 5226
service@de.tuv.com
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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Digital unterschrieben
von Karsten Kluge
Datum: 2024.04.29
10:42:59 +02'00'

i.V. Dr. Karsten Kluge
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
42602123500000001-H4	IIa	Vacuklav 40 B+ Vacuklav 41 B+ Vacuklav 43 B+ Vacuklav 44 B+	HD 1082891-1 #0197
42602123500000002-H7	IIa	Vacuklav 30 B+ Vacuklav 31 B+ Vacuklav 23 B+ Vacuklav 24 B+ Vacuklav 24 BL+ Euroklav 29 VS+ Euroklav 23 VS+ Euroklav 23 S+	HD 1082891-1 #0197
42602123500000006-HK	IIa	MELAquick 12+ MELAquick 12+ p	HD 1082891-1 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
42602123500000007-HN	IIb non-implantable	MELAtherm 10 DTA MELAtherm 10 DTB MELAtherm 10 Evolution DTA MELAtherm 10 Evolution DTB	HD 1082891-1 #0197
Cliniclave 45	IIa	N/A	HD 1082891-1 #0197
Cliniclave 45 M	IIa	N/A	HD 1082891-1 #0197
Cliniclave 45 D	IIa	N/A	HD 1082891-1 #0197
Cliniclave 45 MD	IIa	N/A	HD 1082891-1 #0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/29	MELAG_CL607_2024-04-29	Initial issue
YYYY/MM/DD	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list