k Way
G20

STATE OF UTAH

OFFICE OF THE LIEUTENANT GOVERNOR

Apostille

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

2. This public document has been signed by WILLEM EVAN BARNES

3. Acting in the capacity of NOTARY PUBLIC, STATE OF UTAH

4. Bears the seal/stamp of WILLEM EVAN BARNES, NOTARY PUBLIC, STATE OF UTAH

Certified

5. at Salt Lake City, Utah, U.S.A.

6. the 29th day of April, 2025

7. by Deidre M. Henderson, Lieutenant Governor, State of Utah, U.S.A.

8. Number: 541591

9. Seal/Stamp:

10. Signature

Deidre M. Henderson

Lieutenant Governor

This certification attests only to the authenticity of the signature of the official who signed the affixed document, the capacity in which that official acted, and where appropriate the identity of the seal or stamp which the document bears. This certification is not intended to imply that the contents of the document are correct, nor that they have the approval of the State of Utah.

LIGER MEDICAL
Innovation for Better Women's Health

3300 North Running Creek Way
Building G, Basement Suite G20
Lehi, Utah 84043
United States of America

801-256-6576

www.ligermedical.com

CE Mark CE 669605: Extension and Transition Compliance Explanation

24 April 2025

To whom it may concern:

I am writing to provide clarification regarding the status of our CE mark CE 669605 and its validity for our Class IIa legacy device. While the original CE mark has technically expired, we have received a formal extension granted by our notified body, BSI (notified body number 2797). This extension ensures that the CE mark remains valid until December 31, 2028, in accordance with Article 97 and EU Regulation 2023/607, which amends EU Regulation 2017/745.

This extension allows us to maintain compliance during the transition from the EU Medical Device Directive (MDD) to the EU Medical Device Regulation (MDR). Our notified body issued a letter confirming the extension, enabling us to continue placing our legacy device on the European market while aligning with the MDR requirements. We have already submitted our new technical file for review in advance of the May 26, 2024, deadline, demonstrating our proactive efforts to meet the updated regulatory standards under the MDR framework. Please see the following documents for validity of the extension:

- Exhibit 1: BSI EU 2023/607 Notified Body Confirmation Letter
- Exhibit 2: Manufacturer's Declaration pursuant to EU Regulation 2023/607
- Exhibit 3: Application of EU Regulation 2017/745, Article 97
- Exhibit 4: EC Certificate – Full Quality Assurance, CE 669605

We trust this explanation and the accompanying documentation will address any concerns regarding the validity of our CE mark. Please find enclosed a copy of the letters from BSI and other supporting materials for your reference.

Should you require any further information or have additional questions, please do not hesitate to contact me directly. I am available to assist and provide any additional details you may need.

Yours sincerely,

LIGER MEDICAL ★ UTAH ★ INCORPORATED ★ est. 2011

Timothy Pickett 4/24/2025

Timothy Pickett, P.E. Date
Director of Regulatory and Quality
Liger Medical

State of Utah
County of Utah

On this 24 day of April, 2025,
personally appeared Timothy Pickett
(Name of signer)
proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he/she executed the same.

Willem Barnes

Notary Public
My commission expires: 12/26/2028

WILLEM EVAN BARNES
Notary Public, State of Utah
Commission # 740817
My Commission Expires On
December 26, 2028

Exhibit #1

EU Regulation 2023-607 Notified Body Confirmation Letter

Letter from Notified Body

BSI: NB # 2797

Exhibit #7

EU Regulation 2023-607 Notified Body Confirmation Letter

Letter from Notified Body

BSI: NB # 2797

Liger Medical
3300 North Running Creek Way
Building G, Basement Suite G20
Lehi, Utah 84043
USA

15-April-2025

Notified Body Confirmation Letter
Reference: EU2023-607/1139689

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

Liger Medical
3300 North Running Creek Way
Building G, Basement Suite G20
Lehi, Utah 84043
USA
SRN Number: US-MF-000042429

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 of the

corresponding devices 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 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer 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 the 20 Mar 2023 for the relevant devices.

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:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 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 BSI Group The Netherlands B.V.,

Graeme Tunbridge

Graeme Tunbridge
Senior Vice President, Medical Devices

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
HTU-110 Thermocoagulator	Class IIa	N/A	CE 669605 with expiry date: 2022-12-07 NB#: 2797

Table 2: Devices covered by this letter and for which the NB is NOT 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	Action
2025/04/15	Initial issue

Exhibit #2

Manufacturer's Declaration pursuant to EU Regulation 2023/607

Exhibit #2

Manufacturer's Declaration pursuant
to EU Regulation 2023/607

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

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

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- 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	Liger Medical
Manufacturer address and contact details	3300 North Running Creek Way Building G, Basement Suite G20 Lehi, Utah 84043 USA Timothy.pickett@ligermedical.com
Single Registration Number (SRN) (if available)	US-MF-000042429

Authorised Representative name (if applicable)	Mednet EC-REP IIb GmbH
Authorised Representative address and contact details	Brookstrasse, 10, Munster, Germany adina.wagner@medneteurope.com
Single Registration Number (SRN) (if available)	DE-AR-000011192

Notified body name (if applicable)	BSI Group The Netherlands B.V.
Notified body number (if applicable)	2797
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 669605
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	07 December 2022

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

End date of extended validity/transition period	31 December 2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- 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(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☑ Expired *before* 20 March 2023:

  ☑ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

- ☐ Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  - ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  - ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☐ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☐ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 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.

☑ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) 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:	Liger Medical
Location & Date:	3300 North Running Creek Way, Building G, Basement Suite G20, Lehi, Utah 84043, USA
Signature/Date Print Name, Title	Timothy Pickett 26 September 2024 Timothy Pickett, Director of Quality and Regulatory
Contact Details (at least email)	timothy.pickett@ligermedical.com (+1 801-256-6576)

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
HTU-110 Thermocoagulator (Class IIa)	CE 669605	07 December 2022	BSI Group The Netherlands B.V. (2797)	BSI Group The Netherlands B.V. (2797)	31 December 2028	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Exhibit #3

Application of EU Regulation 2017/745
Article 97

Letter from Notified Body

BSI: NB# 2797

Exhibit #3

Application of EU Regulation 2017/745

Article 97

Letter from Notified Body

BSI: NB# 2797

bsi. Inspiring trust for a more resilient world.

Liger Medical LLC
3300 North Running Creek Way
Building G
Lehi
Utah
84043
USA

7 February 2023

Our ref: CE 669605

Expiry date: 07 December 2022

To whom it may concern,

Information to support the application of Article 97 of the Medical Device Regulation (EU 2017/745) to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

This letter is issued pursuant to the publication of MDCG 2022-18.

Confirmation

This letter confirms that the above-mentioned certificate:

- is a certificate issued under the requirements of the Medical Device Directive (93/42/EEC) (the "MDD");
- covers "legacy devices" (as described by MDCG 2021-25 and to which Article 120 (3) of the Medical Device Regulation (EU2017/745) applies) (the "MDR") that are in transition from the MDD to the MDR or for which the relevant conformity assessment procedure required pursuant to the MDR has not been concluded;
- has either expired by course of time (and was valid at the date of its expiry, it neither having been suspended nor withdrawn), or is to expire shortly (and remains valid at the date of this letter).

It is not possible to provide an estimated timescale by when conformity assessment under the MDR will be complete as there are many factors that affect this. However, the average duration from signing a contract with BSI Group to issuance of an MDR certificate is 15 months.

Assumptions

BSI Group is issuing this letter on the following assumptions. BSI Group requires the manufacturer to inform it immediately if any of these assumptions are incorrect:

- the only non-conformity to which the above-mentioned devices are subject is that the certificate referred to above has either expired or is about to expire, without the immediate availability of a replacement certificate issued under the MDR;
- the manufacturer (or its authorised representative) has informed the relevant Competent Authority of this non-conformity, accompanied with a report containing relevant data including that concerning incidents and field safety corrective actions, to permit the Competent Authority to evaluate risk to the health and safety of patients;
- the Competent Authority will evaluate the risk associated with the devices to determine if there is no unacceptable risk to patient health or safety and thereby whether Article 97 may apply to the devices covered by the MDD certificate.

Conditions

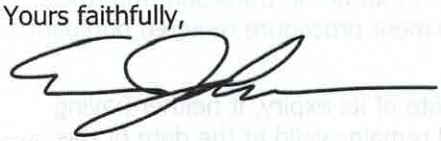
This letter is issued subject to the following conditions:

- that the assumptions above remain correct at all times;
- that the manufacturer (or its authorised representative) provides to the relevant Competent Authority any relevant information relating to the devices that demonstrate that the evaluation of the Competent Authority (that the devices do not present an unacceptable risk to patient health or safety) may need to be re-evaluated;
- that the manufacturer provides to BSI Group a copy of any authorisation granted by a Competent Authority under Article 97 of the MDR.

Providing these conditions are met, BSI Group will commit to providing the relevant Competent Authority information relating to any major safety-related shortcomings identified during conformity assessment under the MDR.

This confirmation letter remains valid for so long as the manufacturer continues to apply to meet the requirements of conformity assessment under the MDR, within the scope of a contract for such services it has with BSI Group.

Yours faithfully,



Eric Johnson
Scheme Manager / Technical Specialist, Active Devices

Exhibit #4

Original:

EC Certificate – Full Quality Assurance

CE669605

Exhibit #4

Original:

EC Certificate – Full Quality Assurance

CE669605

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 669605**

Issued To: **Liger Medical LLC**

3300 North Running Creek Way
Building G
Lehi
Utah
84043
USA

In respect of:

Design and Manufacture of Thermal Ablation Devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2017-12-08** Date: **2019-02-14** Expiry Date: **2022-12-07**

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bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 669605**
Date:	**2019-02-14**
Issued To:	**Liger Medical LLC**
	3300 North Running Creek Way **Building G** **Lehi** **Utah** **84043** **USA**

Subcontractor:	**Service(s) supplied**
SMIDGEN Millhouse, Bleach Rd. Kilkenny, Ireland	**EU Representative**

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bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669605**
Date: **2019-02-14**
Issued To: **Liger Medical LLC**

3300 North Running Creek Way
Building G
Lehi
Utah
84043
USA

Date	Reference Number	Action
8 December 2017	8694370	First issue.
Current	8694380	Traceable to NB 0086.

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