

FORM CSF410-TCB FCC APPLICATION FORM

This form constitutes the certification agreement between Element Materials Technology and the Applicant and is required for every application. Please ensure accuracy when completing this form because the content is used to make the FCC upload to the FCC eFiling system.

Please complete the relevant sections in the tables below. Guidance on each numbered section of this form is provided at the end of the document. Please contact Element if you have any further questions.

Applicant business details	
1. Applicant's complete, legal business name.	CMR Surgical Ltd
2. Applicant's mailing address (Line 1)	1 Evolution Business Park
3. Applicant's mailing address (Line 2)	Milton Road
4. City, State, Zip (or postal code)	Cambridge, Cambridgeshire, CB24 9NG
5. Name, Title of Person registered with the FCC to receive the grant.	Chanel Allen-Megahey
6. Phone No. (Area/Country /City Code, Number, Ext).	+44 7845 014416
7. Fax No. (Area/Country/City Code, Number, Ext).	
8. Internet email address	chanel.allen-megahey@cmrsurgical.com
9. Applicants FRN # (FCC registered number)	0030112320

Authorised agent details <i>Only to be completed where a third party is used to make an application on behalf of the Applicant</i>	
10. Name, Title	
11. Mailing address (Line 1)	
12. City, State, Zip (or postal code)	
13. Phone No. (Area/Country /City Code, Number, Ext).	
14. Internet email address	

Product details	
15. Equipment model	MA-0382-5 J8 to J9-11 Assembly
16. FCC ID Number GRANTEE CODE	2ASDB
17. FCC ID equipment code (Max. 14 Chars.)	MA-0382-5
18. FCC ID Rule part. (15.249, 15.247, etc.)	15.225

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19. Type of grant	☒ Original Grant ☐ Class II Permissive Change ☐ Class III Permissive Change ☐ Change in ID (Provide original FCC ID number and grant date (yyyy/mm/dd:))
20. Seeking modular approval?	☒ Yes ☐ No
21. Contain a pre-approved radio module?	☐ Yes ☒ No If yes, FCC ID of pre-approved module:
22. Are there provisions for using this radio within 20 cm of the head or torso? (belt clips, holster, headset, etc.)	☒ Yes ☐ No

Other information	
23. Do you wish to hold some information permanently confidential?	☒ Yes ☐ No
24. Do you wish to hold some information confidential short-term?	☐ Yes ☒ No

Notes or comments
Free field

FCC application and signature

Read each certification carefully before answering and signing this application.

WILLFUL FALSE STATEMENTS MADE ON THIS FORM ARE PUNISHABLE BY FINE AND/OR IMPRISONMENT (U.S. CODE, TITLE 18, SECTION 1001), AND/OR REVOCATION OF ANY STATION LICENSE OR CONSTRUCTION PERMIT (U.S. CODE, TITLE 47, SECTION 312(a)(1)), AND/OR FORFEITURE (U.S. CODE, TITLE 47, SECTION 503).

25. SECTION 5301 (ANTI-DRUG ABUSE) CERTIFICATION

The applicant must certify that neither the applicant nor any party to the application is subject to a denial of Federal benefits, that include FCC benefits, pursuant to Section 5301 of the Anti-Drug Abuse Act of 1988, 21 U.S.C. §862 because of a conviction for possession or distribution of a controlled substance. See 47 CFR 1.2002(b) for the definition of a "party" for these purposes.

Does the applicant or authorized agent so certify?

☒ Yes

☐ No

26. NOT PREVIOUSLY SUBMITTED NOR DENIED

I certify that this product has not been previously submitted to the FCC nor to another TCB for certification. I further certify that this product has not previously been dismissed nor denied by the FCC nor by another TCB.

27. APPLICANT/AGENT ATTESTATION

I certify that I am authorized to sign this application. All of the statements herein and the exhibits attached hereto are true and correct to the best of my knowledge and belief. In accepting a Grant of Equipment Authorization issued by the TCB as a result of the representations made in this application, the applicant is responsible for (1) labeling the equipment with the exact FCC ID specified in this application, (2) compliance statement labeling pursuant to the applicable rules, and (3) compliance of the equipment with the applicable technical rules. If the applicant is not the actual manufacturer of the equipment, appropriate arrangements have been made with the manufacturer to ensure that production units of this equipment will continue to comply with the FCC's technical requirements.

Authorizing an agent to sign this application, is done solely at the applicant's discretion; however, the applicant remains responsible for all statements in this application.

If an agent has signed this application on behalf of the applicant, a written letter of authorization which includes information to enable the agent to respond to the above Section 5301 (Anti-Drug Abuse) Certification statement has been provided by the applicant. It is understood that the letter of authorization must be submitted to the FCC upon request, and that the TCB reserves the right to contact the applicant directly at any time.

28. IEC/ISO 17065 REQUIREMENTS

By signing this application, the applicant agrees to the following requirements and conditions:

- a. The applicant will always comply with the relevant provisions of the certification programme, and the requirements of the regulatory body under which certification is granted, including implementing appropriate changes when they are communicated by the Element Certification Body.
- b. If the certification applies to ongoing production, the certified product continues to fulfil the product requirements.
- c. The applicant will make all necessary arrangements for:
 - i) the conduct of the evaluation, including provision for examining documentation and records and access to and access to the relevant equipment, location(s), area(s), personnel, and applicant's subcontractors;
 - ii) investigation of complaints;
 - iii) the participation of observers, if applicable.
- d. The applicant makes claims regarding certification consistent with the scope of certification.
- e. The applicant will not use its product certification in such a manner as to bring the Element Certification Body into disrepute and will not make any statement regarding its product certifications, which the Element Certification Body may consider misleading or unauthorized.
- f. The applicant will, upon suspension, withdrawal, or termination of certification, discontinue its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure
- g. If the applicant provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme.
- h. In making reference to its product certification in communication media such as documents, brochures or advertising, the applicant will comply with the requirements of The Element Certification Body or as specified by the certification scheme.
- i. The applicant will comply with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product
- j. Applicant is required to maintain a record of all complaints made known to Applicant that relate to the compliance of the device described in this application with the requirements of the relevant standards for certification. Applicant will make such records available to the Element Certification Body upon request. In addition, Applicant is required to take appropriate actions with respect to such complaints and any deficiencies found in the device pursuant to such complaints and to document any corrective action taken.
- k. The applicant will inform the Element Certification Body, without delay, of changes that may affect its ability to conform to the certification requirements.
- l. The certification body at Element is self-funding from the certificates that it issues. Element maintains adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations, and has the financial stability and resources required for its operations. Fees for certification activities are applied on a project by project basis according to established fee schedules. Certification fees vary with the complexity of the project.
- m. Applicant will pay all fees in association with the application and ongoing certification activities such as surveillance and product modification;

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29. MARKET SURVEILLANCE

The applicant will maintain a production sample of the device for at least one year after the last production date for the purposes of evaluation, surveillance and resolution of complaints, as required by the FCC or equivalent foreign regulatory body.

30. COMPLAINT OR DISPUTE

In the event that the applicant has a complaint or a disagreement with the findings of the Element Certification Body, the complaint or appeal may be filed with the Element Certification Body by informing the Element Certification Body via written notification by either email or letter. In the event the original decision is upheld, the applicant may elect to accept or reject the finding. If the finding is accepted, then the applicant may respond to the finding by providing the necessary information which would result in a positive certification decision. If the finding is rejected then the governing agency who granted authority to the certification body shall be arbitrator of the dispute and the decision made by that body shall decide the outcome.

31. CONDITIONS FOR REVOCATION

- a. Unless prohibited by the Certification Regulations, Applicant's certification is revocable for cause, which includes, but is not limited to, the following:
 - i) The Element Certification Body is directed to revoke certification by the regulatory body.
 - ii) Applicant instructs the Element Certification Body in writing to revoke certification for a Device.
 - iii) Applicant fails to comply with the Certification Regulations of the Countries.
 - iv) Applicant fails to pay any fees required by this Agreement.
 - v) Applicant breaches any of the terms, conditions or specifications listed in this Agreement.
- b. In the event that applicant's certification is nullified or revoked, the Element Certification Body will notify the appropriate regulatory authorities that such certification has been nullified or revoked, as the case may be.

32. CONFIDENTIALITY

The Element Certification Body will not disclose to third parties any proprietary technical or financial information marked by Applicant as confidential without Applicant's prior written consent. Please be advised, that due to the Freedom of Information Act, the FCC requires certain information to be placed in the public domain while other competitive information, upon request, can be afforded confidential protection. Reference 47 CFR 0.459 and 0.457(d) and FCC KDB 726920 for details. Other than those documents granted confidential protection by the FCC, all other information that comprises the Applicant's application for certification will be viewable by the public. The Element Certification Body will inform Applicant of all information marked as confidential intended to be disclosed to third parties and will provide Applicant with an opportunity to seek confidential protection of such information. Any documents, reports, drawings, test data, etc., made available to, produced at the request of, or produced by the Element Certification Body may be copied and retained by the Element Certification Body if necessary to the performance of this Agreement or in compliance with the applicable Certification Regulations of the Countries.

Signature

DocuSigned by:

Chanel Allen-Megahey



Signer Name: Chanel Allen-Megahey

Signing Reason: I approve this document

Original signed by: Chanel Allen-Megahey on 2020/10/20 at 10:20:10 -0400

Date (Year-Month-Day)

19D4DCF892224DAF8E551432D6A1C3F0
Chanel Allen-Megahey

Head of Regulatory

Typed/printed name of authorized signer

Title of authorized signer

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Instructions for filling out this application form

Items 1-8: The applicant's mailing address and the person to receive the grant must be identical to the address the FCC has on file for your grantee code. You can check on-line at <https://apps.fcc.gov/oetcf/eas/reports/GranteeSearch.cfm>

Item 9: Your FRN number is the registration number for your company, granted by the FCC. If you have not obtained an FRN number, you can apply for one on line <https://apps.fcc.gov/cores/userLogin.do>

Item 15-18: Make sure this model number is the same for all documentation (user manual, test report, application, etc.) All models marketed with this device must have test report data. Only the model(s) for which test data has been provided will appear on the grant. Please specify the FCC ID for the product and Grantee code belonging to the applicant.

Item 19-22: Please specify the type of grant you are applying for and provide details of any approved radio modules that are in the end device already. All approved modules must have no broken grant notes/restrictions.

Item 23: The FCC allows some information, submitted as exhibits, to be held confidential and thus excluded from public viewing. Exhibits such as schematics, theory of operation, block diagrams may be held confidential. Other exhibits such as photos, user manual, test reports are not allowed to be held confidential. CFR, Title 47 paragraph 0.459 explains the rule regarding confidential material. The complete text can be found on-line at http://www.ecfr.gov/cgi-bin/text-idx?sid=ca225bb5842b8a7230ec3bacf19cbf1e&c=ecfr&tpl=/ecfrbrowse/Title47/47tab_02.tpl

Item 24: In accordance with FCC KDB 726920 Section III exhibits may be held confidential short term for a maximum of 180 days from the date of grant, or until the product is introduced for marketing.
<https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=41731&switch=P>

Items 25-27: The FCC requires that the applicant attest to the elements described. Please read carefully and sign, or have your agent sign.

Items 28-32: The FCC requires TCBs to maintain ISO/IEC 17065 accreditation as a certification body. These items are a requirement of both the FCC and ISO/IEC 17065.

Please read carefully and sign the application, or have your agent sign.

Please upload a completed, signed copy of this form to the applicable project on the Element Certification Tracking System.

This form replaces forms CSF-042 and FR410-TCB