

Guide to Application for IECEE CB Certification

Cosmos Corporation

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I. Introduction

1. About this Guide

This Guide describes the service of issuing CB Test Certificate (hereinafter referred to as "CBTC") under IECEE CB Scheme, which is provided by Cosmos Corporation (hereinafter referred to as "Cosmos"), a National Certification Body (NCB). IECEE CB Scheme is an international system for mutual acceptance of test data according to IEC standards.

Applicants and CB certification holders must consent to the descriptions in this Guide and to observe the requirements at any time. Therefore, even after CB certification is granted, keep this Guide properly for easy reference when necessary.

If you have any question on this Guide or others, contact CS Department or Engineering Department.

II. Process of CB certification

1. Scope of CB certification service

Our CB certification service is available for the following product categories:

- MED (medical devices): IEC 60601-1, IEC 60601-1-6
- MEAS (measurement and laboratory equipment): IEC 61010-1

2. Location and contact to provide CB certification service

CB Certification service is provided at the following offices.

Cosmos Corporation Matsusaka Headquarters

718-1 Katsurase, Matsusaka City, Mie Prefecture 515-1104 Japan

TEL: +81-598-30-5225 FAX: +81-598-30-5571

3. Flow of CB certification service

The steps from application to issue of CBTC and CBTR are as follows:

<Step 1>

Download this Guide and Application Form for CB Certification from our website and complete the Application Form. Send the completed form to us together with documents required for estimation as specified in 5. Documents required for application in this Guide.

<Step 2>

We will calculate CB certification fee according to above information and send an estimate to you.

At that time, we will inform you of necessary information, sample, estimated period for evaluation, applicable standard(s), etc.

In some cases, we may not be able to accept your application.

<Step 3>

Send the signed Application Form for CB Certification (PDF file is acceptable), required documents and test sample(s).

* Contact us if you want to cancel the application. Cancellation fee is charged, if we already receive the signed Application Form for CB Certification.

<Step 4>

The application is formally accepted. We issue an invoice for the half amount of fee and start testing and evaluation of the product applied for.

[In case of nonconformity]

- We will report nonconformity, if any, in an Assessment Report.
- If you do not expect to make improvements but cancel the application, please inform us. The fee for already completed works will be charged, and we will close the project.

<Step 5>

Upon completion of all evaluations, review and decision of certification, we issue CBTC and CBTR.

4. Handling of test sample

We conduct evaluation tests on the test sample(s) according to applicable standard(s).

Note that some of tests such as destructive tests may damage the supplied test sample and test tools.

5. Documents required for application

Download the Application Form for CB Certification from our website. Complete the form and send it to us together with required materials and information listed in the following table.

* The documents marked with a circle (○) are required at the stage of estimation.

* We will inform you of documents required at the stage of evaluation when we send you an estimate.

Document	Remarks	Required at the stage of estimation
Application of CB Certification Work [QAF1862]	Download it from our website.	○
List of factories		
Authorization Letter	It is required, if: ① the Applicant delegates authority concerning the application to an agent; or ② the Applicant differs from the Manufacturer.	
Declaration Letter	It is required only when a trademark different from the Applicant's one is used.	
Manufacturer Declaration	It required only when there is more than one factory.	
Instruction Manual (in English)		○
Rating label	Rating label Please include the following information as applicable: - Product name Model Electrical rating Trademark - Manufacturer's name, etc. - Instructions and graphical symbols for caution and warning - A copy of rating label with its dimension ◆ Indicate the location of labels on the product.	
Installation manual or installation specification	If the product has installation conditions, please provide the document including the following information as applicable: - operating environment (e.g. indoor, outdoor, floor type, tabletop); - specified minimum clearance from peripherals (e.g. wall); - provision of cooling equipment; - ventilation method; - capable to be used in a rack or not; - outer dimension (H x W x D), and so on.	
Service manual	Instructions for service personnel	
Drawing of marking on a package	(in case of application according to IEC 60601-1) Include permissible environmental conditions for transport and storage (temperature, humidity, atmospheric pressure).	
Material of label and ink, or printing method	This information is necessary to be included in CBTR for marking, e.g. rating, cautions specified in the applied standard.	
Instructions for operation at maximum	Method which allows the operator to set and operate the product.	

DCN: QAF1870-1 Issued: 21/05/20 Revised: --/--/-- Translated: 21/05/21

Document	Remarks	Required at the stage of estimation
load	Operating conditions under which the power consumption of the product becomes maximum. The product must operate until the temperature of measuring locations becomes constant. Considering above, please prepare the instructions including the following information as applicable: - maximum loading operation; - setting to achieve maximum continuous automatic loading operation; - maximum operating ambient temperature; - Input voltage tolerance; - installation conditions; - installation condition in normal use of the product; - method for installation and setting of peripherals to be connected the unit	
Critical component list	Download its template from our website.	○
Block diagram		○
Insulation block diagram	Send the diagrams showing the primary circuit, isolation between primary and secondary circuits and between primary circuit and ground, and high voltage parts.	
Circuit diagrams	Send the diagrams showing the primary circuit, isolation between primary and secondary circuits and between primary circuit and ground, and high voltage parts. *If the product is provided with any of the following circuits, send their circuit diagrams: a - Protective circuit for lithium battery b - Interlock circuit c - I/F (interface) circuit d - Inverter board for back light (for LCD, etc.) * Please note that the submitted diagrams have the signatures and dates in the columns of "Approved", "Reviewed", "Designed" and "Prepared" respectively.	○
Pattern diagrams and silk-screens of printed wiring boards	Same as circuit diagrams.	
Appearance drawing of the product	Include the following information as applicable: - outer dimension (H x W x D); - location of labels; - bill of materials [including each part name, manufacturer's name, type designation, material, minimum thickness, non-combustibility (for insulation material only)]; - total weight; - dimension of opening (H x W); - drawings for assembly/disassembly (which help us to understand how to assemble or disassemble each cover)	
License sheets of	IEC or EN standard	

Document	Remarks	Required at the stage of estimation
recognized components	UL standard (certification number is acceptable) CSA standard	
Test report of switching power supply and/or AC adapter	If these components are already approved, please provide the following information: - Copy of CBTC and CBTR	
Risk assessment sheet	Applicable to application for certification to IEC 61010-1 only.	
Risk management file	Applicable to application for certification to IEC 60601-1 only. For evaluation of risk management process, please provide a risk management file according to ISO 14971.	
Risk Management Result Table	Applicable to application for certification to IEC 60601-1 only. Complete relevant pages of CBTR we send.	
Usability engineering file result table	Applicable to application for certification to IEC 60601-1 only. Complete relevant pages of CBTR we send.	
Usability engineering file	Applicable to application for certification to IEC 60601-1 only. For evaluation of usability, send a usability engineering file.	
Result of evaluation of IEC 60601-1, Cl. 14 Programmable electrical medical system	Applicable to application for certification to IEC 60601-1 and the case where programmable electrical medical system (Cl. 14) is used. Complete relevant pages of CBTR we send.	
Interlock system diagram	If an interlock circuit is spilt into several boards, send a drawing briefly describing which board disconnects which supply circuit. Send a drawing briefly describing which board disconnects which supply circuit.	
Structural specification of component parts		
Resin material used for reduction of separation distances (conformal coating)(e.g. potting)	- Manufacturer's name/type designation - Flammability rating - Material - Upper temperature limit	
Information of protective earthing	- Each material (including plating) of terminal, fixing screw, fastener and housing - Diameter and upper temperature limit of protective earthing conductor - Connecting method of protective earthing conductor	
Test report of laser and LED	Applicable to the product using a laser or LED as a light source. - Test report according to IEC/EN 60825-1, or - Test report according to IEC/EN 62471	
CBTC and CBTR of lithium-ion battery	Applicable to the product using a lithium-ion battery. CBTC and CBTR according to IEC 62133	
Sample	At least three units (we will inform you when we issue the formal estimate)	

Document	Remarks	Required at the stage of estimation
	Additional sample may be required depending on product.	
Peripherals to operate the product	Same as the amount of sample	
Single components (for construction check and repair)	We will inform you when we issue the formal estimate.	

6. Change of the contents in the application after receipt of the order of CB certification

If you want to change any of the contents of the application after we receive it (e.g. change of construction, addition of component), you need to request the change to us. Send us corrected Application Form for CB Certification with changes made. Some kinds of change may require additional fee. In such case, we issue an extra estimate or modify the original estimate. Contact us in advance.

7. Confidentiality

We will keep your secrets known in the process of CB certification service strictly confidential. We will not disclose them to third parties, unless such disclosure is requested according to applicable legislations.

8. Consultancy

We do not offer or provide consultancy, because it is prohibited under ISO/IEC 17065.

9. Change and withdrawal of CB certification

(1) Issue of supplement to CBTC, etc.

Apply for change of descriptions in CBTC, etc., if any change is made to CBTC.

- ① Change of address of the Applicant or production manager described in CBTC, etc. (including change of the writing and relocation)
- ② Change of address of the factory described on CBTC, etc. (including change of the writing and relocation)
- ③ Relocation of the factory described on CBTC, etc.
- ④ Addition of other factory to CBTC, etc.
- ⑤ Change of rating on CBTC and CBTR, etc., rating label, critical component, circuit, pattern and appearance

* Such change due to technical changes to the certified product are limited to maximum three times according to the requirements of IECCE OPERATIONAL

DOCUMENT IECEE OD-2020.

- ⑥ Change of construction (e.g. addition of alternate or new component)
 - * Such change due to technical changes to the certified product are limited to maximum three times according to the requirements of IECEE OPERATIONAL DOCUMENT IECEE OD-2020.
- ⑦ Change of trademark, addition of other trademark
- ⑧ Updating the applied standard
(not involving significant revision of CB Test Report Form)
- ⑨ Addition of new model similar to the certified product (meeting the definition in IECEE OPERATIONAL DOCUMENT IECEE OD-2027)

(2) Issue of new CBTC, etc.

Apply for change of descriptions in CBTC, etc., if any change is made to CBTC.

- ① Change of name of Applicant and/or production manager described on CBTC, etc.
- ② The fourth technical change due to change of rating described on CBTC and CBTR, etc., rating label, critical component, circuit, pattern or appearance
- ③ The fourth technical change due to construction change
- ④ Updating the applied standard (involving revision of CB Test Report Form)
- ⑤ Addition of new model similar to the certified product (not meeting the definition in IECEE OPERATIONAL DOCUMENT IECEE OD-2027)

(3) Cancellation of CB certificate

If the mass-produced products do not comply with the assessed test sample and CBTR, we may cancel the granted CB certification. Once cancelled, IECEE will immediately inform the production manager and all other NCBs of the cancellation of CBTC and CBTR concerned and its reason.

III. Service fee and payment

1. Service fee concerning CB certification

We charge the service fee as prescribed (please refer to Annex 1).

2. How to make payment

The half amount of CB certification fee on formal estimate is billed when an application is accepted by us and the remainder is billed after the project is completed. If additional assessment is required due to improvement against nonconformity found by the

evaluation or other reason, an extra fee is charged after completion of assessment.

IV. Rights and obligations of Applicant and CB certification holder

1. Rights of Applicant and CB certification holder

Applicants and CB certification holders have the rights to acquire CB certification objectively, fairly and impartially and to exercise the following rights over Cosmos.

- (1) Challenge to certifier (with due reason)
- (2) Reflection of various circumstances of Applicant or CB certification holder in plan of implementation of assessment (CB certification is granted in the order of agreement formation, unless we must stop the service to the Applicant or CB certification holder for any reason attributable to the Applicant or CB certification holder)
- (3) Safeguarding confidentiality of the Applicant's or CB certification holder's information known in the process of assessment activities for CB certification
- (4) Making an appeal to decision on CB certification
- (5) Making a complaint
- (6) Filing a dispute
- (7) Use of and reference to CBTC and CBTR (for CB certification holder only)

2. Obligations of Applicant and CB certification holder

Obligations of Applicant and CB certification holder are as follows:

- (1) Taking corrective actions on findings arising from the assessment for CB certification and report of these actions to Cosmos
- (2) Providing all documents concerning the application for CB certification and disclosure of records
- (3) Payment of service fee concerning the assessment for CB certification

3. Obligations of CB certification holder

Obligations of CB certification holder are as follows:

- (1) ensuring the certified product always comply with the requirements;
- (2) making records of complaints from customers, including:
 - situation of occurrence;
 - investigation of causes;
 - corrective or preventive actions; and
 - disclosing them to us upon our request;
- (3) avoiding misuse and misleading use of CB certification;

- (4) correct but not misleading reference to CB certification; and
- (5) control of CBTC to avoid unauthorized use.

4. Cancellation of CB certification

If nonconformity to CB certification is proven or we receive a request of cancellation from Applicants, we send a cancellation notice for CB certification.

In addition, we will ask to discontinue the use of all advertisements and promotional materials referencing the CB certification concerned.

5. Registration of CBTC to IECEE Online Database

When we issue CBTC, we will send a confirmation request letter for registration to IECEE Online Database to know your intention of the registration. You may choose non-disclosure. We will register your CBTC according to your request.

V. CB certification holder requirements for maintenance of CB certification

CB certification holders must continuously comply with all the following requirements and have a procedure to always keep the information provided for us updated.

1. Change of or addition to the scope of CB certification for the product

(1) CB certification holders must inform our CS Department of any of the following change and addition before doing it. In such case, please be sure to attach a document clearly describing the point of change and reason.

(a) Change of the information of CB certification holder and/or factory in the application (e.g. addition, relocation, change of parcel number or withdrawal)

(b) Change concerning the conformity to standard for CB-certified product (change of product specification, rating, component, etc.)

(c) Change of the contents of registration of CB-certified model

(d) Cancellation of registration of CB-certified model

(2) Use of CBTC

CB certification holder must avoid unauthorized use of copy of CBTC.

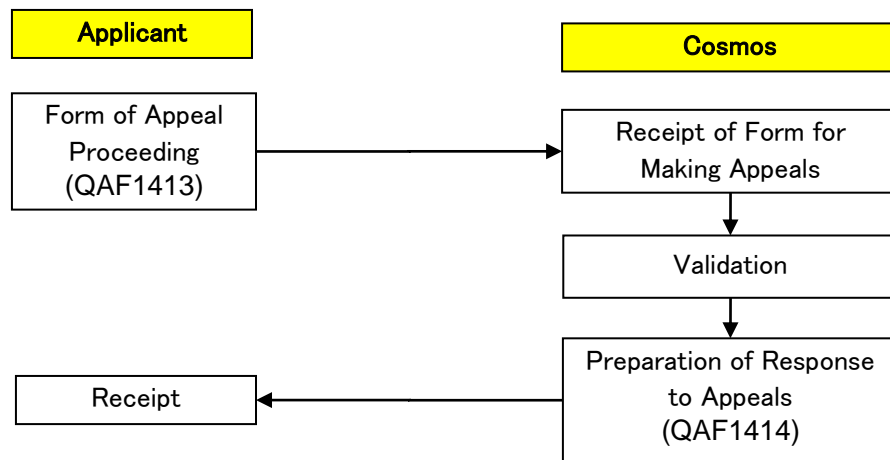
VI. Complaints and appeals

Applicants are encouraged to contact our CS Department for complaints on evaluation and CB certification in general and appeals against our decision on CB certification.

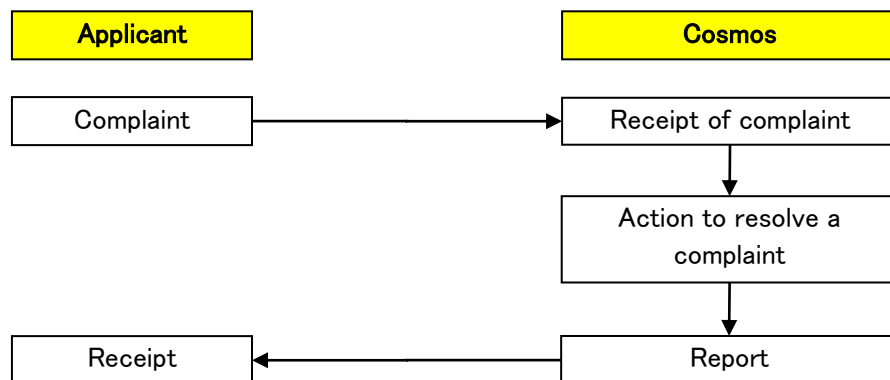
For appeals, we will send a Form for Making Appeals to understand the details of appeal. Complete and send it back to us.

After we receive it, we will respond to it later.

1. Flow of making an appeal



2. Flow of handling a complaint



Annex 1 Service fee for CB certification

The service fee for CB certification is calculated according to the following tables.

■新規

Brand-new

Title Contents	費用 (消費税別) Fees (Consumption tax is not included)	Remarks Note
技術費用 Engineering fee	弊社料金算出規定によります。 Our rule on estimate shall apply	製品・評価内容などにに基づき時間工数で算出致します。 Calculate by time man-hours based on product and evaluation contents
試験費用 Testing fee	弊社料金算出規定によります。 Our rule on estimate shall apply	製品・評価内容などにに基づき時間工数で算出致します。 Calculate by time man-hours based on product and evaluation contents
製品書類審査料 Document assessment fee	技術費用+試験費用の 20%となります。(最低 100,000 円) 20% of Engineering fee + Testing fee (Min. 100,000 JPY)	技術費用+試験費用の 20%が 100,000 円を下回る場合は 100,000 円を適用致します。 Apply 100,000 JPY when the 20% of Engineering fee + Testing fee becomes less than 100,000 JPY
CB 証明書発行手数料 CB certificate issuance fee	60,000 円 60,000 JPY	証明書発行、維持管理、IECEE への支払費用含みます。 Including issuance of certificate, maintenance, payment for IECEE

■技術的変更

Technical modification

試験有りの場合

With testing

Title Contents	費用 (消費税別) Fees (Consumption tax is not included)	Remarks Note
技術費用 Engineering fee	弊社料金算出規定によります。 Our rule on estimate shall apply	製品・評価内容などにに基づき時間工数で算出致します。 Calculate by time man-hours based on product and evaluation contents
試験費用 Testing fee	弊社料金算出規定によります。 Our rule on estimate shall apply	製品・評価内容などにに基づき時間工数で算出致します。 Calculate by time man-hours based on product and evaluation contents
製品書類審査料 Document assessment fee	技術費用+試験費用の 20%となります。(最低 80,000 円) 20% of Engineering fee + Testing fee (Min. 80,000 JPY)	技術費用+試験費用の 20%が 80,000 円を下回る場合は 80,000 円を適用致します。 Apply 80,000 JPY when the 20% of Engineering fee + Testing fee becomes less than 80,000 JPY
CB 証明書発行手数料 CB certificate issuance fee	60,000 円 60,000 JPY	証明書発行、維持管理、IECEE への支払費用含みます。 Including issuance of certificate, maintenance, payment for IECEE

■技術的変更

Technical modification

試験無しの場合

Without testing

Title Contents	費用 (消費税別) Fees (Consumption tax is not included)	Remarks Note
技術費用 Engineering fee	弊社料金算出規定によります。 Our rule on estimate shall apply	製品・評価内容などにに基づき時間工数で算出致します。 Calculate by time man-hours based on product and evaluation contents
試験費用 Testing fee	0 円 0 JPY	試験は要求されません。 No testing required
製品書類審査料 Document assessment fee	技術費用+試験費用の 20%となります。(最低 80,000 円) 20% of Engineering fee + Testing fee (Min. 80,000 JPY)	技術費用+試験費用の 20%が 80,000 円を下回る場合は 80,000 円を適用致します。 Apply 80,000 JPY when the 20% of Engineering fee + Testing fee becomes less than 80,000 JPY
CB 証明書発行手数料 CB certificate issuance fee	60,000 円 60,000 JPY	証明書発行、維持管理、IECEE への支払費用含みます。 Including issuance of certificate, maintenance, payment for IECEE

■管理上の変更（工場追加等）

Administrative modification (addition of factory etc.)

Title Contents	費用（消費税別） Fees (Consumption tax is not included)	Remarks Note
技術費用 Engineering fee	弊社料金算出規定によります。 Our rule on estimate shall apply	製品・評価内容などにに基づき時間工数で算出致します。 Calculate by time man-hours based on product and evaluation contents
試験費用 Testing fee	0 円 0 JPY	試験は要求されません。 No testing required
製品書類審査料 Document assessment fee	技術費用+試験費用の 20%となります。 (最低 10,000 円) 20% of Engineering fee + Testing fee (Min. 10,000 JPY)	技術費用+試験費用の 20%が 10,000 円を下回る場合は 10,000 円を適用致します。 Apply 10,000 JPY when the 20% of Engineering fee + Testing fee becomes less than 10,000 JPY
CB 証明書発行手数料 CB certificate issuance fee	60,000 円 60,000 JPY	証明書発行、維持管理、IECEE への支払費用含みます。 Including issuance of certificate, maintenance, payment for IECEE

■その他

Others

- Non-CB メンバーの国に所在する Applicant, Manufacturer, Factory の場合、20,000 円が別途必要となります。
For Applicant, Manufacturer and Factory of non-CB members, 20,000 JPY is required separately.
- 1 モデルにつき 1 ライセンスが発行されます。
One license is issued for one model.
- トレードマークまたはブランドネームが複数ある場合、各トレードマークもしくはブランドネームにつき 1 ライセンス発行されます。
For more than one trademark or brand name, one license is issued for each trademark or brand name.
- 2枚以上の証明書発行時は、追加証明書1枚あたり 12,000 円が別途必要となります。
When two or more certificates are issued, 12,000 JPY per additional certificate is required.