

## **INFORMATION NOTE FOR APPLICANTS**

### **FOR A CB TEST CERTIFICATE OR FOR RECOGNITION OF CB TEST CERTIFICATE**

#### **CONFORMITY ASSESSMENT CERTIFICATES FOR ELECTROTECHNICAL EQUIPMENT AND COMPONENTS**

LNE  
Ref. written by Thierry Thomas – LNE

Initial document - March 2007  
Modified document – February 2008  
Approved by Laurence Dagallier : 2008-02- 22

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#### **Reference documents:**

- **IECEE 01 - IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) – Basis Rules**
- **IECEE 02 – Scheme of the IECEE for Mutual Recognition of test certificates for Electrotechnical Equipment and Components (CB Scheme) – Rules of Procedure**

**Who should you contact?**

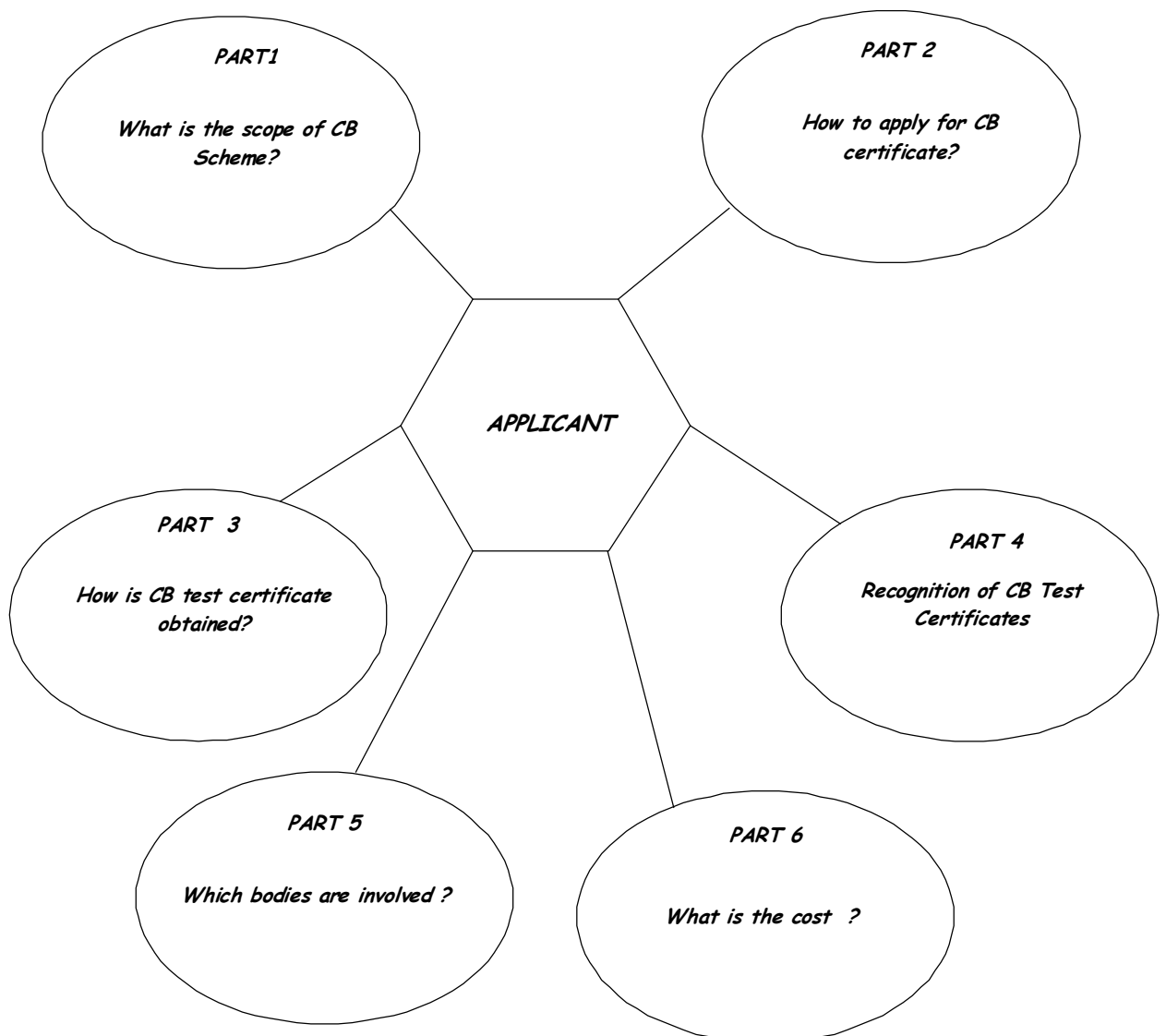
Laboratoire national de métrologie et d'essais (LNE)  
Business Development and Certification Department (DDC)  
1, rue Gaston Boissier -75724 PARIS CEDEX 15  
Internet site: [www.lne.fr](http://www.lne.fr)

**Your sales contact:**

**Bruno TRENI**  
Tel.: 01 40 43 39 02  
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**Your technical contact:**  
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## UPDATING

<b>Certification regulations</b>	<b>Reason for update</b>	<b>Revision</b>	<b>Date</b>
<b><u>Part 1:</u></b> <b>Scope –CB Scheme</b>			
<b><u>Part 2:</u></b> <b>Quality requirements</b>			
<b><u>Part 3:</u></b> <b>Obtaining certification</b>			
<b><u>Part 4:</u></b> <b>Recognition of CB Test certificates</b>			
<b><u>Part 5:</u></b> <b>Participating organizations</b>			
<b><u>Part 6:</u></b> <b>Applicable fees – Terms of payment</b>			

## **1. WHAT IS THE SCOPE OF THE CB SCHEME?**

### **1.1 Scope**

The CB Scheme is based on the use of CB test Certificates which provide evidence that representative specimens of the product have successfully passed tests to show compliance with the requirements of the relevant IEC standards.

An application for obtaining a CB Test Certificates is intended to reduce obstacles to international trade which arise from having to meet different national certification or approval criteria.

This document based on IECEE02 (Scheme of the IECEE for Mutual Recognition of Test Certificates for Electrotechnical Equipment and Components (CB Scheme) – Rules of Procedure), gives the information on LNE's scope for recognition and issuing CB test certificates, on the process to obtain a CB test certificate and condition for recognition by LNE of a CB test certificate.

CB Test Certificates could be issued for the following list of standards related to electromedical devices :

- IEC 60601-1 ed 2  
Medical electrical equipment – Part 1 : General requirements for basic safety and essential performance
- IEC 60601-1-1  
Medical electrical equipment – Part 1-1 : General requirements for safety – Collateral standard : Safety requirements for medical electrical systems
- IEC 60601-1-2  
Medical electrical equipment – Part 1-2 : General requirements for safety – Collateral standard : Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-3  
Medical electrical equipment – Part 1-1 : General requirements for safety 3– Collateral standard : General requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-2-7  
Medical electrical equipment – Part 2-7 : Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
- IEC 60601-2-18  
Medical electrical equipment – Part 2 : Particular requirements for the safety of endoscopic equipment. Includes NF EN 60601-2-18 (01/01/1997) and NF EN 60601-2-18/A1 (01/02/2006)
- IEC 60601-2-32  
Medical electrical equipment – Part 2 : Particular requirements for the safety of associated equipment of X-ray equipment
- IEC 60601-2-38  
Medical electrical equipment – Part 2 : Particular requirements for the safety of electrically operated hospital beds  
Includes NF EN 60601-2-38 (01/12/1999) and NF EN 60601-2-38/A1 (01/02/2006)
- IEC 60601-2-43  
Medical electrical equipment – Part 2-43 : Particular requirements for the safety of X-ray equipment for interventional procedures

## **2. HOW TO APPLY FOR A CB TEST CERTIFICATE?**

### **2.1 Requirements applicable to the Applicant**

The applicant may be a manufacturer or act on behalf of a manufacturer. On the latter case, evidence shall be submitted that the applicant is authorized to act on behalf of the manufacturer for the application and that the manufacturer undertakes the same obligations as the applicant.

The applicant will be the holder of the CB Test Certificate.

Any manufacturer wishing to obtain a CB Test Certificate for its product must first carefully read this information note. More information about CB scheme can be found on the IECEE website ([www.iecee.org](http://www.iecee.org)).

The application is drawn up on the applicant's headed paper and using the application form. It must be sent to LNE.

The application to LNE shall contain as a minimum the following information :

- Name and address of the applicant
- Name and address of the manufacturer, if different from the applicant
- Names and addresses of the factories where the product is manufactured. If several facilities involved, the equivalence between the products need to be demonstrated by the manufacturer
- Mark, trade marks or other markings by which the applicant, the manufacturer, when appropriate, and the factory can be unambiguously identified by LNE
- Type and designation and markings by which the product can be unambiguously identified by LNE
- Identification of the relevant standards used as a base for the test to be carried out by the LNE's accepted Testing Laboratory.
- Specific test requests to cover national differences in countries in which the CB test certificate is to be used. If additional tests have been carried out, a report of the results may be attached to, and considered to be a part of the test report.

All the documents must be written in French or English.

The purchase order corresponding to the quotation issued by LNE is necessary to begin the assessment (see annex 6)

Documents to be supplied

- Application form (annex to this document)
- Dimensioned drawing of all the products,
- The diagrams required for verifying electrical safety and electromagnetic compatibility.
- Functioning of the products and instruction for use.

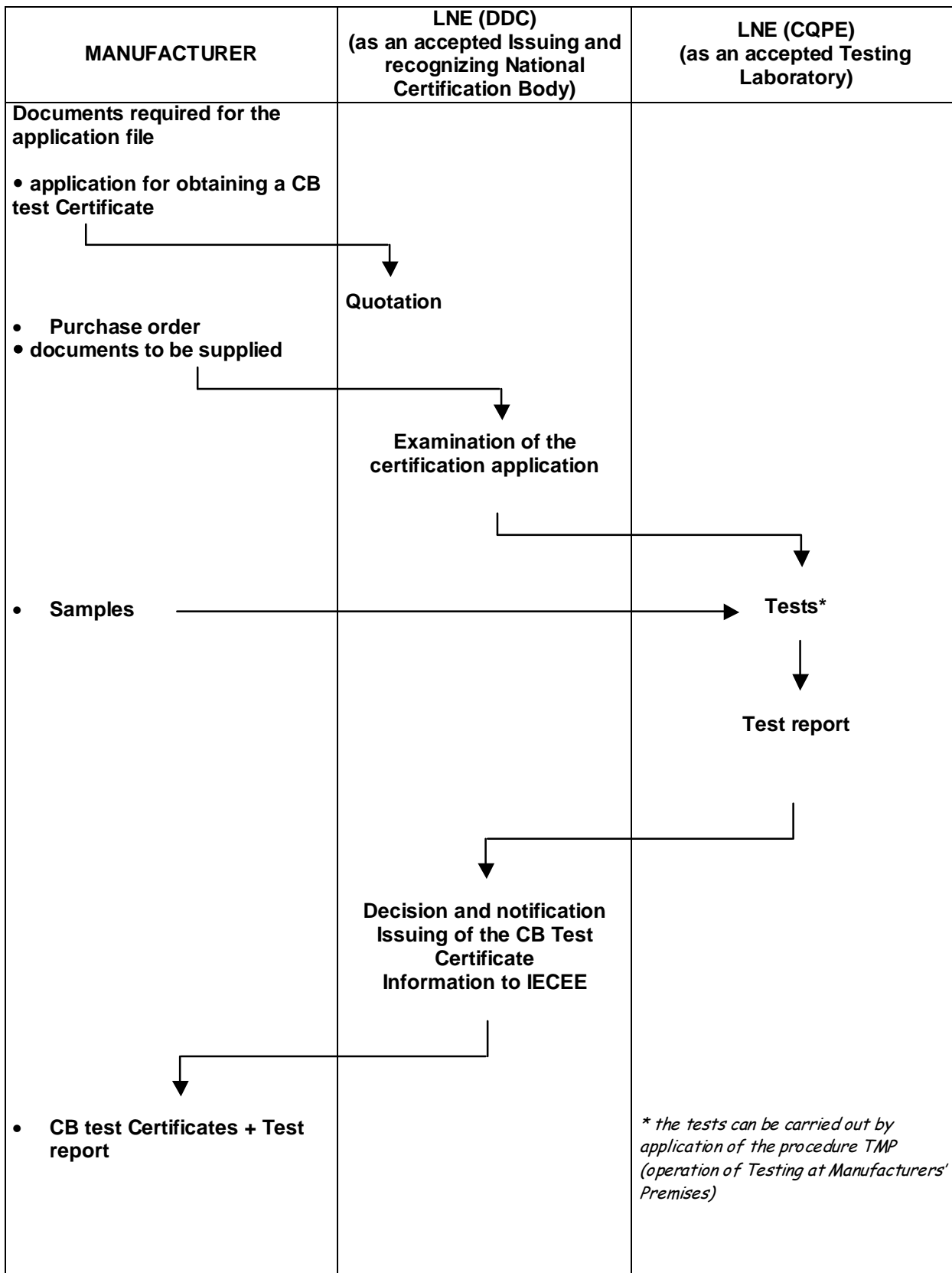
**2.2 Requirements applicable to LNE**

Upon receipt of an application for a CB Test Certificate, LNE shall within one month

- arrange for testing of the relevant equipment
- send the corresponding quotation to the applicant
- start the test after having received a formal order from the applicant

The application, the results of the work done and the information obtained in connection with the application for a CB Test Certificates are kept confidential by LNE.

**3. PROCESS FOR OBTAINING A CB TEST CERTIFICATE**



### **3.1. Examination of the certification application**

The version of applied CB Scheme requirements is the one in force at the date of the quotation. The technical file and the purchase order are sent to the LNE. The file is examined before carrying out tests.

If some elements do not correspond to the requirements of the certification regulations, the LNE informs the applicant and requests missing information. Tests are initiated once a new file is presented and assessed to be complete.

When the file is complete, the number of samples necessary to carry out the tests is confirmed and the necessary information given to the applicant.

### **3.2. Tests**

Tests of conformity to the applicable standards are performed by LNE's laboratories (Centre de Qualification des Produits et Equipements /CQPE) on the products delivered by the manufacturer.

Samples must be delivered directly to the testing laboratory carriage-free and customs-cleared if necessary, within 15 days at most from the time of sampling.

A test report is drawn up for the tests and sent by the Testing Laboratory to the LNE.

In case of testing performed at the manufacturer premises, the manufacturer is responsible for :

- Demonstrating that the facilities are in compliance with the relevant requirements of ISO/IEC 17025
- Appointing an appropriate person to be responsible for the facilities and/or services provided to the LNE.

### **3.3. Issuing of the CB certificate by LNE**

At reception of the Test Report , LNE examines the document, verifies that the format of the report is in compliance with the format included in the list of available and recognize IECEE test format report and if test results are favourable issues the CB Test certificate within 15 working days from the receipt of the test report.

### **3.4 Modification to issued CB Test certificate**

A new CB test certificate is issued (new reference n°) when there is a new edition or amendment of applied standard

The CB test certificate shall be re-issued with the same reference n° and a new revision suffix when there is some misprints, changes of names and addresses.

Modifications on certified product are limited to 3, after which a new CB test certificate shall be issued.

Any change related to the items provided in the application form or to the device shall be declared to LNE. LNE performs appropriate assessment (including tests if necessary) in order to issue a modified or a new certificate.

### **3.5 Cancellation of a CB Test certificate**

A CB test certificate may be cancelled in case of :

- the certificate is misused,
- the certificate has been issued in error,
- the equipment no longer corresponds to the specimens tested and described in the attached test reports,
- the holder of the certificate requests cancellation.



When an applicant applies for a NF Mark certification or EC type or design examination to LNE, the application may be provided with a copy of a CB Test Certificate with the attached Test Report and, if relevant, with attached reports covering national differences.

If the tests standards identified in the CB Test Certificate are in the CB recognising scope of LNE, LNE takes into account the results of the test in its assessment related to a NF Mark certification or EC type or design examination.

- LNE may require specimen of product if deemed necessary.
- The applicant shall follow the procedure applicable to the NF Mark certification or EC type or design examination and shall confirm readiness to comply with all the relevant additional provisions.
- The LNE examines the submitted CB Test Certificate and report and any required specimen to the extent considered for the identification of the relevant equipment and for the recognition of the CB Test Certificate.
- LNE informs the applicant of the possibility to recognise the CB Test Certificate and associated report within 15 working days.
- If the result of this examination is favourable, and after the whole assessment is carried out and favourable, NF Mark certification or EC type or design examination are granted by LNE without additional testing. If the test report does not cover declared French differences, these should first be tested. The LNE retains the right to test further the equipment to ascertain whether or not the equipment complies with the relevant standard.
- The LNE may challenge the CB Test Certificate when it is more than three years old when the standard according to which it was issued is no longer in force in France.
- The LNE may keep for reference photographs, technical documentation and specimens or, for large equipments, parts of such equipment. Such reference material are confidential.

## **5. PARTICIPATING ORGANIZATIONS**

### **5.1. Issuing and recognizing National Certification Body**

**LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS (LNE)**  
**Business Development and Certification Department (DDC)**

1, rue Gaston Boissier  
75724 PARIS CEDEX 15  
Tel. 01 40 43 37 00

### **5.2 CB Testing Laboratory**

The LNE entrusts the tests to the laboratory named below:

**LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS (LNE)**

- ✓ **Qualification Center for Products and Equipment**  
 29, avenue Roger Hennequin  
 78197 TRAPPES Cedex  
 Tel. 01.30.69.10.00

**6. APPLICABLE FEES – TERMS OF PAYMENT**

**6.1 Applicable fees**

Fees for the services involved in obtaining a CB Test certificate is indicated in a list of charges which may be revised annually.

An applicant in a country with no Member Body of the IECEE, and an applicant acting on behalf of a manufacturer in such a country shall pay a contribution to the costs of the IECEE in the form of surcharge for each CB Test Certificate issued, the amount to be decided by the IECEE. The surcharge is to be collected by LNE, and remitted to the IECEE account. These costs are given in CH francs.

The LNE fees are given in Euros, tax excluded.

With regard to test fees, samples must be delivered to the testing laboratory carriage-free and customs-cleared if necessary, within 15 days at most from the time of sampling.

**6.1.1 Fees for obtaining a CB test certificate**

Examination of the Testing report and issuing of a CB Test Certificate..... 650 €

**6.1.2 Fees for each type of test**

Tests of conformity with a relevant standard (see scope Part 1) and report..... By estimate

**6.1.3 Surcharge to be collected by LNE handling the application**

The following table gives the different combination of Applicant “A”, Manufacturer “M” and Factory “F” that are subjected to surcharge (150 CHF each). The surcharge is to be collected by the LNE, and remitted to the IECEE account upon invoicing by the IECEE Secretariat. The surcharge is not applicable in case of modification of a CB Certificate (limited to 3 modifications)

In a member Country	In a non-member Country	Surcharge
AMF	None	No
AMF	F	Yes
AMF	M	Yes
AMF	MF	Yes
AM	M	Yes
AM	MF	Yes
AM	F	Yes

In a member Country	In a non-member Country	Surcharge
AF	MF	Yes
AF	M	Yes
AF	F	Yes
MF	AMF	Yes
MF	AM	Yes
MF	AF	Yes
F	A	Yes
F	AMF	Yes
F	AM	Yes
F	AF	Yes

## 6.2 Terms of payment

### 6.2.1 Collecting payment

LNE is empowered to collect all payments.

Invoices issued by the LNE must be paid within 45 days.

The applicant or holder must settle these invoices under the terms set out: any failure on the part of the holder will prevent the LNE from exercising the operating responsibilities incumbent on it by virtue of these regulations.

If the first enforcement order, sent by registered letter with acknowledgement of receipt, does not result in payment of the total amount due within one month, the LNE will be entitled to take measures of conservation.

### 6.2.2 Invoicing schedule

The services payable for each factory are issuing of a CB Test certificate and the tests performed on the samples.

The test fee is payable once the laboratory in charge of the test is in possession of the samples.

No fees relating to examination of the application can be refunded, regardless of the result of the examination.

ANNEX I

DEMANDE DE CERTIFICATION PRODUITS  
(A établir sur papier à en-tête du demandeur)

A l'attention de  
Monsieur le Directeur Général du LABORATOIRE NATIONAL  
DE METROLOGIE ET D'ESSAIS  
Direction Certification  
1, rue Gaston Boissier  
75724 PARIS CEDEX 15

**OBJET** : Demande de Certificat selon la méthode OC (CB Test Certificate) pour des équipements électromédicaux et composants

Monsieur le Directeur Général,

Je soussigné (*nom et fonction*) .....  
représentant l'Entreprise (*raison sociale - siège social*).....  
.....demande au LNE de procéder aux vérifications nécessaires en vue de la certification de  
produit dans le cadre de la certification OC (CB Scheme certification) du dispositif électromédical (*type de dispositifs et  
référence commerciale*).....  
conformément à la (aux) norme(s) suivante(s) (*cocher les référentiels demandés*) :

- IEC 60601-1 ed 2 : Appareils électromédicaux - Partie 1: Exigences générales pour la sécurité de base et les performances essentielles,
- IEC 60601-1-1: Appareils électromédicaux - Partie 1-1: Règles générales de sécurité - Norme collatérale: Règles de sécurité pour systèmes électromédicaux,
- IEC 60601-1-2 : Appareils électromédicaux - Partie 1-2: Règles générales de sécurité - Norme collatérale: Compatibilité électromagnétique - Exigences et essais,
- IEC 60601-1-3 : Appareils électromédicaux - Partie 1: Règles générales de sécurité - 3. Norme collatérale: Règles générales pour la radioprotection dans les équipements à rayonnement X de diagnostic,
- IEC 60601-2-7 : Appareils électromédicaux - Partie 2-7: Règles particulières de sécurité pour générateurs radiologiques de groupes radiogènes de diagnostic,
- IEC 60601-2-18: Medical electrical equipment – Part 2 : Particular requirements for the safety of endoscopic equipment. Includes NF EN 60601-2-18 (01/01/1997) and NF EN 60601-2-18/A1 (01/02/2006)
- IEC 60601-2-32 : Appareils électromédicaux - Partie 2: Règles particulières de sécurité pour les équipements à rayonnement X,
- IEC 60601-2-38 : Appareils électromédicaux - Partie 2: Règles particulières de sécurité des lits d'hôpital électriques, Inclus NF EN 60601-2-38 (01/12/1999) et NF EN 60601-2-38/A1 (01/02/2006),
- IEC 60601-2-43: Appareils électromédicaux - Partie 2-43: Règles particulières de sécurité pour les appareils radiologiques lors d'interventions,

et selon les dispositions prévues par les règles de certification établies dans le cadre de la certification OC (CB Scheme certification).

Je m'engage à respecter les dispositions de la note d'information et du document IECCE 02 – IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components. Rules of procedures.

Fait à ....., le .....

Cachet du demandeur  
et signature de son représentant

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**Annex 2**

**BULLETIN D'IDENTIFICATION**

(A établir sur papier à en-tête du demandeur)

(à établir et à compléter par le demandeur et à joindre à son dossier)

- Coordonnées du demandeur (siège social)

. Nom :  
. Adresse :  
. Contact :  
. Téléphone :  
. Fax :  
. e mail :

- Coordonnées du fabricant (si différente) :

. Nom :  
. Adresse :  
. Contact :  
. Téléphone :  
. Fax :  
. e mail :

- Coordonnées de(s) usine(s)\* ou est fabriqué le dispositif :

. Nom :  
. Adresse :  
. Contact :  
. Téléphone :  
. Fax :  
. e mail :

\* si le dispositif est fabriqué dans différents sites, l'équivalence entre les dispositifs doit être démontrée et documentée dans le dossier de demande de certificat selon la méthode OC (CB Test Certificate)

- Nom, nom commercial ou autres moyens par lesquels le fabricant peut être identifié sans ambiguïté

- Les références commerciales et/ou numéro, désignation, marques, par lesquels le dispositif peut être identifié sans ambiguïté

Date  
Cachet et signature  
du demandeur

**FORM No. 1**

**APPLICATION FOR ADMISSION**

(to be drawn up on the manufacturer's headed paper)

Director General of  
LABORATOIRE NATIONAL DE  
METROLOGIE ET D'ESSAIS  
Direction Certification  
1, rue Gaston Boissier  
75724 PARIS CEDEX 15

**PURPOSE:** Application for a CB Test Certificate for electromedical devices and components

Dear Sir

I the undersigned (name and position) .....  
representing the company (identification of the company - registered office).....  
request the LNE to carry out the verifications required for obtaining a CB Test Certificate for the electromedical  
device (type of device, reference).....  
.....  
according to the following standard(s) (tick the boxes) :

- IEC 60601-1 ed 2 : Medical electrical equipment – Part 1 : General requirements for basic safety and essential performance
- IEC 60601-1-1: Medical electrical equipment – Part 1-1 : General requirements for safety – Collateral standard : Safety requirements for medical electrical systems
- IEC 60601-1-2: Medical electrical equipment – Part 1-2 : General requirements for safety – Collateral standard : Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-3: Medical electrical equipment – Part 1-1 : General requirements for safety 3– Collateral standard : General requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-2-7: Medical electrical equipment – Part 2-7 : Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
- IEC 60601-2-18: Medical electrical equipment – Part 2 : Particular requirements for the safety of endoscopic equipment. Includes NF EN 60601-2-18 (01/01/1997) and NF EN 60601-2-18/A1 (01/02/2006)
- IEC 60601-2-32: Medical electrical equipment – Part 2 : Particular requirements for the safety of associated equipment of X-ray equipment
- IEC 60601-2-38: Medical electrical equipment – Part 2 : Particular requirements for the safety of electrically operated hospital beds. Includes NF EN 60601-2-38 (01/12/1999) and NF EN 60601-2-38/A1 (01/02/2006).
- IEC 60601-2-43: Medical electrical equipment – Part 2-43 : Particular requirements for the safety of X-ray equipment for interventional procedures,

and according to the provisions of the rules of CB scheme certification.

I undertake to comply with the provisions of the information note and the document IECEE 02 – IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components. Rules of procedures.

Date  
Stamp and signature  
of the agent's applicant

**FORM No. 2**

**IDENTIFICATION FORM**

(to be drawn up on the manufacturer's headed paper)

(to be established and completed by the applying manufacturer and to be enclosed to their file for application)

- Applicant's details (head office)

- . Name
- . Contact person
- . Address
- . Telephone
- . Fax
- . E-mail

- Manufacturer's details (if different)

- . Name
- . Contact person
- . Address
- . Telephone
- . Fax
- . E-mail

- Manufacturing premises\* where the device is manufactured

- . Name
- . Contact person
- . Address
- . Telephone
- . Fax
- . E-mail

\* : if the device is manufactured in several premises, the equivalence between devices from the different plants shall be demonstrated and documented in the CB Test certificate application file.

- Name, Trade name and references and/or number (etc...) to precisely identified the device without ambiguity
- Name, Trade name (etc...) to precisely identified the manufacturer without ambiguity.

Date  
Stamp and signature  
of the agent's applicant