

Your contact :

Customer service

Tél./Fax : +33 1 40 43 37 11 / 37 37

email : legal.metrology@lne.fr

Purpose of this questionnaire

Have information on your company management system to help us to establish a certification offer.

COMPANY IDENTIFICATION

- Legal name :
 - Adress :
 - Tel :
 - Company identification number in your country (or VAT number for European country) :
 - Code NACE :
- Name of LNE main contact person :
 - Position : _____ E-mail : _____

REFERENTIALS REQUESTED FOR CERTIFICATION

☞ Management systems – All sectors

- ISO 9001** – Quality management system - Requirements
- ISO 14001** – Environmental management system – Requirements with guidance for use
- OHSAS 18001** – Occupational health and safety management systems. Guidelines for the implementation of OHSAS 18001
- ILO** – Guidelines on Occupational Safety and Health Management Systems
- OHSAS 18001 and ILO**

☞ Specific management systems

- **Measuring Instruments**

- Legal metrology – Measuring instruments subject to regulations** – National regulation and CE marking.

- **Healthcare and medical devices field.**

- Regulatory** - CE Marking of medical devices – Australia
- ISO 13485** – Medical devices - Quality management systems – Requirements for regulatory purposes
 - Within the framework of Canadian regulations (CMDCAS)
 - Within the framework of Taiwan regulations
- ISO 13485 - for sterilisation activities** in addition to standards ISO 11135 – 1 (EtO) / ISO 11137 – 1 (irradiation) and ISO 17665 – 1 (moist heat)

Packaging field

- ISO 15378** – Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP)
- ISO 22000** – Food safety management systems – Requirements for any organization in the food chain
- BRC/IOP** – British Retail Consortium/ Packaging
- FEFCO/ESBO** - International GMP Standard For Corrugated & Solid Board
- EN 15593** - Management of hygiene in the production of packaging for foodstuffs

For each selected referential, please fill in the relevant annex..

Information contained in this questionnaire is considered as confidential by LNE representatives who are bound by professional secrecy

Laboratoire national de métrologie et d'essais

Établissement public à caractère industriel et commercial • Siège social : 1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00

Fax : 01 40 43 37 37 • E-mail : info@lne.fr • Internet : www.lne.fr • Siret : 313 320 244 00012 • NAF : 743 B • TVA : FR 92 313 320 244

Barclays Paris Centrale IBAN : FR76 3058 8600 0149 7267 4010 170 BIC : BARCFRPP

SCOPE INTENDED TO BE COVERED BY THE CERTIFICATION

- Which activities, processes and product categories are to be covered by the certificate you are applying for (activity to appear on the certificate)?
- What are the activities performed within the certification scope ?

<input type="checkbox"/> Design	<input type="checkbox"/> Purchasing	<input type="checkbox"/> Production
<input type="checkbox"/> services	<input type="checkbox"/> Marketing <small>(products manufactured by the company)</small>	<input type="checkbox"/> Trade <small>(products purchased to be sold)</small>
<input type="checkbox"/> Storage	<input type="checkbox"/> Distribution (logistic)	<input type="checkbox"/> Testing and control
<input type="checkbox"/> Other(s) :		
- Are activities/processes subcontracted/outsourced? Yes No
If yes, specify :
- If your request concerns several referential, are the management systems integrated ? Yes No
If Yes, specify :

Please enclose a description sheet of your company.

DESCRIPTION OF SITES TO BE COVERED BY THE CERTIFICATION YOU ARE APPLYING FOR

- How many site(s) are covered by the considered certification?

Name of site	Address	Activities	Number of staff *	Certification referential

*equivalent number of full time employees including staff on a fixed term contract, temporary staff, onsite subcontractors – Staff affected by the activities covered by the considered certification (including support activities).

- Do you wish all sites to be covered by a single certificate? yes No
- Do you have a common management system for all sites? Yes No
- Are similar activities carried out on each site? Yes No
- Do several teams perform the same type of activity? (2x8, 3x8) Yes No

If yes, please fill in the table below:

shift (times)	Number of employees/shift

INFORMATION ON COMPANY AND ITS MANAGEMENT SYSTEM

- Does your company belong to a group?
 No Yes. Specify

- Is your company a holder of (a) certificate(s)? Please specify:

CERTIFICATION ⁽¹⁾	Certification body	Expiry date

(1): management system certification (ISO 9001, ISO 13485, ISO 14001, ISO 22000, etc) and/or product certification (NF marking, LNE packaging, BRC, etc) and/or regulatory certification (CE marking, etc.)

- Do you wish your current certificate to be transferred? Yes No
- Did your company receive guidance/ assistance for setting up the considered certification within the last 3 years?
 No Yes, Specify the service provider:
- Requested service(s)
 - Do you request a pre-audit? ("mock audit" independent from the certification process)
 Yes No
 - Do you wish to achieve joint product certification? ¹
 No Yes, Specify referential:
 - What is your proposed time period for the certification audit (Specify month) ?
 - Are you interested in other LNE services (training, tests, calibration...)?
 No Yes, Specify :
- Have you done this year or the year before :
 - Internal audit(s) : yes No
 - Management review(s): yes No

I hereby certify that information contained in this questionnaire is truthful and request a certification offer by LNE on the basis of this information.

Date:

Signature of company representative:

Note : This questionnaire should be returned to the contact person mentioned in page 1. For all additional information, please contact them.

ANNEX
ADDITIONAL INFORMATION ON YOUR MANAGEMENT SYSTEM

ISO 9001 CERTIFICATION
Quality Management System

- Have activities been excluded from the certification scope to be covered? yes No

If yes, list the activities excluded?

Justification of exclusions :

ISO 14001 OR FD X 30 205 CERTIFICATION Environmental Management System

- Status of your environmental management system:

Is there existing documentation? Yes No. What is the due date?

Is the system operational? Yes No. When is the due date?

- Infrastructures:

- Surface of grounds :

- Surface of buildings :

- Production related activities and equipment presenting a possible risk to the environment:

Hydrocarbon tank

Refrigerated unit (air conditioning or cooling)

Storage of chemicals

Other. Give details:

Air compressor

Water treatment plant

Boiler

Battery charger

Waste zone

Drilling

Please enclose a detailed map of the site in the appropriate format.

- Regulatory status:

- Is the site subject to:

A declaration?

An authorisation?

If applicable, is the site subjected to a prefect order?

Yes No, if applicable, indicate progress

Seveso status

If applicable, tick the relevant box : low threshold
 High threshold

Please enclose a list of Seveso installations for the site, as well as the thresholds reached

- Regulatory situation for a site located abroad

- Is the site subject to

An autorisation from local authorities

An autorisation from national authorities

Seveso

If applicable, tick the relevant box : low threshold
 High threshold

Please enclose the regulatory approvals concerning the site

OHSAS 18001 or ILO-OSH CERTIFICATION

health and safety management systems

- Status of your health and safety management systems:

Is there existing documentation? Yes No. What is the due date?

Is the system operational? Yes No. When is the due date?

- Building site currently:

- Are there building site opened ? Yes No.

If yes, complete the table below :

SUBJECT	ACTIVITIES CARRIED OUT	DURATION	NUMBER OF STAFF INVOLVED

- Are there building site closed and independent? Yes No.

If yes, complete the table below :

SUBJECT	ACTIVITIES CARRIED OUT	DURATION	NUMBER OF STAFF INVOLVED

- Details about number of staff:

	ACTIVITIES	NUMBER OF STAFF
FUNCTIONS HOSTED ON THE SITE		
PERMANENTS PROVIDERS ON THE SITE*		
EMPLOYEES OFF-SITE**		

* for example : Restaurants, parks, maintenance...

** for example: delivery driver, commercial, after-sales service...

- During the past 3 years, which were are the professional diseases and work accidents reported on your site?

year	PROFESSIONAL DISEASES	WORK ACCIDENTS

- Regulatory situation for a site located abroad

- Is the site subject to

The french regulations

The regulations of the country

- What is the staff rattachement? (expatriate,...)

PACKAGING FIELD

ISO 22000 CERTIFICATION food safety management systems

- Status of your food safety management system:
 - Have you chosen or established your prerequisite programme(s)? Yes No
If yes, which one(s):
 - Have you performed a risk analysis/HACCP?
 - No. What is the due date?
 - Yes. How many critical control points(CCP)²/prPo³ have you identified?
 - Is there existing documentation? Yes No. What is the due date?
 - Is the system operational? Yes No. What is the due date?
- Precisions on the activity covered by the application for certification:
 - What are your manufacturing processes?
 - What types of products (materials and packaging) do you produce?

Please enclose a manufacturing chart for your activity.
- Infrastructures:
 - How large are the buildings?
 - How many production lines do you have?
 - Do you have an internal testing laboratory?

PACKAGING FIELD

BRC/IoP CERTIFICATION Quality and Hygiene Management Systems

- Your Quality and Hygiene Management Systems is integrated into another Management system ?

Yes No If yes, which one(s):

What are the chapters in common?

Management commitment, quality policy	<input type="checkbox"/> yes <input type="checkbox"/> No
Planning, objectives, program	<input type="checkbox"/> yes <input type="checkbox"/> No
Resources and responsibility	<input type="checkbox"/> yes <input type="checkbox"/> No
Competence, training and awareness	<input type="checkbox"/> yes <input type="checkbox"/> No
Communication	<input type="checkbox"/> yes <input type="checkbox"/> No
Documentation, control of documents and records	<input type="checkbox"/> yes <input type="checkbox"/> No
Monitoring and measurement	<input type="checkbox"/> yes <input type="checkbox"/> No
Nonconformity, corrective action and preventive action	<input type="checkbox"/> yes <input type="checkbox"/> No
Internal audit	<input type="checkbox"/> yes <input type="checkbox"/> No
Management review	<input type="checkbox"/> yes <input type="checkbox"/> No

- Status of your environmental management system:

- Have you performed a risk analysis/HACCP?(Hazards Analysis and Critical Control Points)

No. What is the due date?

Yes. How many critical steps have you identified?

- Your risk analysis, have she helped to exclud requirements from the certification scope to be covered ?

No

yes. Which one(s) :
Justification :

- Do you have a pest control plan? Yes No
- Have you identified the regulatory requirements applicable to your products? Yes No
- Have you set up a cleaning plan for your facilities and premises? Yes No
- Have you set up arrangements for glass control in production zones? Yes No
- Have you set up arrangements for blunt objects control in production zones? Yes No

- Precisions on the activity covered by the application for certification:

- What are your manufacturing processes?
- What is the risk category of your products? 1 (high risk)
 2 (medium risk)
 3 (low risk)

Please enclose a manufacturing chart for your activity.

- Infrastructures:

- How large are the buildings?
- How many production lines do you have?
- Do you have an internal testing laboratory?

PACKAGING FIELD

FEFCO/ESBO* CERTIFICATION Hygiene Management Systems

- Status of your hygiene management system (HMS):

- Is there existing documentation? Yes No. What is the due date?
- Is the system operational? Yes No. What is the due date?
- Do you have a pest control plan? (Critical criterion section 3.2.1) Yes No
- Have you set up a cleaning plan for your facilities and premises? (Critical criterion section 3.1.1) Yes No
- Have you set up arrangements for glass and brittle objects in production zones? (Critical criterion section 2.3.1) Yes No
- Have you identified catering areas in production zones? (Critical criterion section 4.3.1) Yes No
- Have you banned smoking in production zones? (Critical criterion section 4.5.1) Yes No

- Infrastructures:

- How large are the buildings?
- How many production lines do you have?
- Do you have an internal testing laboratory?

*FEFCO : Fédération européenne des fabricants de cartons ondulés

ESBED : European Solid Board Association

PACKAGING FIELD

EN 15593 CERTIFICATION Management of hygiene in the production of packaging for foodstuffs

- Your Quality and Hygiene Management Systems is integrated into another Management system ?

Yes No If yes, which one(s):

What are the chapters in common?

Management commitment, quality policy	<input type="checkbox"/> yes <input type="checkbox"/> No
Planning, objectives, program	<input type="checkbox"/> yes <input type="checkbox"/> No
Resources and responsibility	<input type="checkbox"/> yes <input type="checkbox"/> No
Competence, training and awareness	<input type="checkbox"/> yes <input type="checkbox"/> No
Communication	<input type="checkbox"/> yes <input type="checkbox"/> No
Documentation, control of documents and records	<input type="checkbox"/> yes <input type="checkbox"/> No
Monitoring and measurement	<input type="checkbox"/> yes <input type="checkbox"/> No
Nonconformity, corrective action and preventive action	<input type="checkbox"/> yes <input type="checkbox"/> No
Internal audit	<input type="checkbox"/> yes <input type="checkbox"/> No
Management review	<input type="checkbox"/> yes <input type="checkbox"/> No

- Status of your environmental management system:

- Have you performed a risk analysis/HACCP?(Hazards Analysis and Critical Control Points)

Yes

No. What is the due date?

- Your risk analysis, have she helped to exclude requirements from the certification scope to be covered ?

No

yes. Which one(s) :

Justification :

- Do you have a pest control plan? Yes No
- Have you identified the regulatory requirements applicable to your products? Yes No
- Have you set up a cleaning plan for your facilities and premises? Yes No
- Have you set up arrangements for glass control in production zones? Yes No
- Have you set up arrangements for blunt objects control in production zones? Yes No

- Precisions on the activity covered by the application for certification:

- What are your manufacturing processes?

Please enclose a manufacturing chart for your activity.

- Infrastructures:

- How large are the buildings?
- How many production lines do you have?
- Do you have an internal testing laboratory?

HEALTHCARE AND MEDICAL DEVICES

ISO 13485 CERTIFICATION and CE Marking Medical devices – Quality management systems

↵ Application for ISO 13485 certification

- Have you excluded any activity from the scope of certification to be covered? Yes No

- Reminder : requirements of 7.3 of standard ISO 13485 can only be excluded when permitted by the regulations (see foreword, standard ISO 13485 and 1.2). In all other cases, the exclusion of a requirement should be justified by the company (see 4.2.2 in ISO 13485)

- What are/is the activity/ies excluded?

- Justification for exclusions:

provided by regulations (ISO 13485 :2003 or NF EN ISO 13485 : 2004)

other, justify:

↵ Application for ISO 13485 certification within the framework of CMDCAS (Canada)

Fill out the following sections below: « *Medical devices concerned* », « identification of main subcontractors », and « sterilisation »

↵ Application for regulatory certification

- Medical devices concerned

Medical device (s) Trade name + category Join a list on a separate sheet if needed	Sterile				Measuring function	Medicinal substance	Product of animal origin	Own Brand Labeling ¹	Classification		GMDN Code ²
	EtO	Irradiation	steam	Other					Europe ³	Canada ⁴	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

¹ Medical device EC marked by your subcontractor, put on the market under the name of your company.

² Canadian PNC code, SPN or ISO/TS 20225 (2001) or AFNOR document FD CR 14230 – Doc. ID S 99-010

³ according to annex IX of Directive 93/42/EEC

⁴ according to article 6 of Canadian Regulations on Medical Instruments (RIM).

HEALTHCARE AND MEDICAL DEVICES

- Identification of main subcontractors (join a list on a separate sheet if needed)

NAME	ADDRESS	ACTIVITIES	Certified quality system
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No

* join enclose a copy of the certificates

- Sterilisation

Does your company have an integrated sterilization unit? : Yes* No

*Specify the type(s) of sterilization:

☞ European regulations : CE marking

If the required annexes are not the same for all the medical devices mentioned below, enclose a separate sheet with details for each medical device.

- In vitro diagnostic medical devices

<input type="checkbox"/> Directive 98/79/EC relating to in vitro diagnostic medical devices	
List A-annex II	<input type="checkbox"/> Annex IV.3 (full quality assurance system without design examination) + Annex IV. 4 (Design examination)*
	<input type="checkbox"/> Annex V (EC type examination)* + Annex VII (production quality assurance system)
List B-annex II	<input type="checkbox"/> Annex IV. 3 (full quality assurance system without design examination)
	<input type="checkbox"/> Annex V (EC type examination)* + Annex VI (Verification CE)*
	<input type="checkbox"/> Annex V (EC type examination)* + Annex VII (production quality assurance system)
Devices for self-diagnosis auto diagnostics (apart from lists of annex II)	<input type="checkbox"/> Annex III. 6 (design examination of devices intended for auto-diagnosis)*
	<input type="checkbox"/> Annex IV.3 (full quality assurance system without design examination) + Annex IV. 4 (design examination)*
	<input type="checkbox"/> Annex V (EC type examination)* + Annex VII (production quality assurance system)

Annexes III.6 (design examination of devices intended for auto-diagnosis), IV.4 (design examination) , V (type examination) and VI (EC verification) are processed independently. In that case, please contact your contact person mentioned in page 1 of this questionnaire.

- Medical devices (other than active implantable and in vitro diagnostic)
The choice of an assessment procedure depends on the medical device class defined according to annex IX of Directive 93/42/EC
- Active implantable medical devices: same choice as for class III

HEALTHCARE AND MEDICAL DEVICES

<input type="checkbox"/> Directive 93/42/EEC relating to medical devices <input type="checkbox"/> Directive 90/985/Ec relating to active implantable medical devices	
class 1- Sterile	<input type="checkbox"/> Annex V limited to aspects of the manufacturing process designed to secure and maintain a sterile condition <input type="checkbox"/> Annex IV limited to aspects of the manufacturing process designed to secure and maintain a sterile condition <input type="checkbox"/> Annex VI limited to aspects of the manufacturing process designed to secure and maintain a sterile condition
Class 1 - with one or more measuring functions	<input type="checkbox"/> Annex IV limited to the control of the measuring function <input type="checkbox"/> Annex V limited to the control of the measuring function <input type="checkbox"/> Annex VI limited to the control of the measuring function
Class IIa	<input type="checkbox"/> Annex II.3 (full quality assurance system without design examination) <input type="checkbox"/> Annex IV (EC verification)* <input type="checkbox"/> Annex V (product quality assurance system) <input type="checkbox"/> Annex VI (product quality assurance system)
Class IIb	<input type="checkbox"/> Annex II.3 (full quality assurance system without design examination) <input type="checkbox"/> Annex IV (EC verification) + Annex III (EC type examination)* <input type="checkbox"/> Annex V (product quality assurance system) + Annex III (EC type examination)* <input type="checkbox"/> Annex VI (product quality assurance system) + Annex III (EC type examination)
Class III and active implantable medical devices	<input type="checkbox"/> Annex II.3 (full quality assurance system without design examination) + Annex II.4 <input type="checkbox"/> Annex IV (EC verification) + Annex III (EC type examination)* <input type="checkbox"/> Annex V (product quality assurance system) + Annex III (EC type examination)*

* Annexes II.3 (design examination) , III(type examination) and IV (EC verification) are processed independently. In that case, please contact your contact person mentioned in page 1 of the questionnaire.

• Australian regulations

Application for a certificate of conformity to Australian regulatory requirements Yes No
 (With reference to the annexes mentioned above)

Does not apply to medical devices:

- Incorporating products of animal or human origin
- Incorporating medicinal products
- Incorporating blood
- Derived from microbiological fermentation
- Containing radioactive materials
- Intended for in vitro diagnosis

• Certification according to Taiwanese regulations

HEALTHCARE AND MEDICAL DEVICES

Do you require a cover letter in the context of Taiwan's Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports? Yes No

The audit will be performed by a team of specially trained auditors.

The audit report will be drawn up in English.

NOTE : This service is reserved for companies located on the territory of one the European Union member state

Legal metrology – Measuring instrument subject to regulations Approval of quality systems and CE marking

- Referentials requested for certification

National regulations :

- Decree n° 2001-387 of 3 May 2001, Order of 31 December 2001 and category-based application regulations for:
- the manufacture of one or more of the instrument categories covered by the provisions of the Decree*
 - the repair of one or more of the instrument categories covered by the provisions of the Decree*
 - the installation of one or more of the instrument categories covered by the provisions of the Decree*.

* Note: The Decision of 29 October 2004 (ISO 9001:2000 applied to legal metrology) sets out the detailed requirements applicable to the quality assurance systems of companies that manufacture, repair or install controlled measuring instruments in the framework of the above-mentioned reference documents. The Decision may be consulted online at : http://www.lne.fr/fr/metrologie/metrologie_legale/documentation-ligne.asp

European regulations :

- European Directive 90/384/EEC amended by Directive 93/68/EEC/ Annex(es) : II.2 in the prospect of CE marking of non automatic weighing instrument des instruments
- European Directive : 2004/22/EC (MID) for CE marking of one or more of the instrument categories covered by the Directive:

Reminder : The choice of one conformity assessment procedure depends on the measuring instrument category . The table below shows the possible options for each measuring instrument category (coloured boxes)

Assessment modules of Directive 2004/22/EC		A1**	D1	E1	F1**	B+F	B+D	B+E	H	H1	G**
Water meters						<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
Gas meters and volume conversion devices						<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
Active electrical power meter						<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
Thermal power meter						<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
Continuous and dynamic measuring devices for fluids other than water						<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
Automatic weighing instruments	Mechanical		<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Electro-mechanical					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Electronic or integrating a software					<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Taximeters						<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
Materialised measurements			<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Dimensional measurements	Mechanical or electro-mechanical instruments		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Electronic instruments or integrating a software					<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
Gas analyser						<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	

A1: Internal control of product manufacturing and testing by a notified body
 B: type examination
 D: manufacturing process quality assurance – conformity to type
 D1: manufacturing process quality assurance
 E: Quality assurance of finished product inspection and testing – conformity to type
 E1: Quality assurance of finished product inspection and testing

F: product verification – conformity to type
 F1: product verification
 G: verification per item
 H: full quality assurance
 H1: full quality assurance and design control

*The (B) type examination is processed independently. Please contact your contact person for type examination applications.

** Please contact your contact person if you have chosen one of these modules

Legal metrology – Measuring instrument subject to regulations Approval of quality systems and CE marking

The standard used to establish the quality assurance system conformity to the requirements of the previously mentioned annexes is EN ISO 9001, version 2000. The guides for applying modules and procedures D and H1 published by WELMEC (<http://www.welmec.org>) are used by LNE for auditing.

- Measuring instrument intended to be CE marked or with French national mark 'à la bonne foi' by the manufacturer

Identification of measuring instruments <i>Enclose list on a separate sheet if necessary</i>	Trade designation of the type	Reference number of type examination, approval, CE type examination certificates, or number of instrument design examination certificate	Primary verification completed	
			In the workshop (*)	On the installation site (*)
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>

(*) tick the relevant box

- Identification of main subcontractors

NAME	ADDRESS	ACTIVITIES	Certified quality system*
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No

* enclose copy of the certificate

- Existing quality documentation :

- Quality manual : Yes No
- Manufacturing, repair, installation procedures: Yes No
- Regulatory brand management procedures: Yes No
- Primary verification procedure : Yes No