



MANAGEMENT SYSTEM CERTIFICATION QUESTIONNAIRE

Your Account Manager:

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Questions?
Contact your Account Manager listed or feel free to call our technical team at (301) 495-0477.

Purpose of this Questionnaire

This application allows our technical team to fully understand and address your certification needs in order to provide a customized service proposal. Should you have any questions or need assistance completing this application, please contact your Account Manager listed above for assistance.

You need only complete the portions of this application relevant to your desired certification, as described in each section. See the last page for additional certifications available and signature.

COMPANY IDENTIFICATION

- Company Name: _____
Street Address: _____
City: _____ State _____ Zip Code _____
Company identification number (VAT number for European country): _____
NACE Code: _____
- Main Contact: _____ Title: _____
Direct Phone: _____ E-mail: _____

REFERENCES REQUESTED FOR CERTIFICATION

Healthcare and Medical Devices Field

- Regulatory - CE Marking of medical devices
- ISO 13485 – Medical devices - Quality management systems – Requirements for regulatory purposes
 - Within the framework of Canadian regulations (CMDCAS)
- ISO 9001 – Quality management system - Requirements
- ISO 13485 - for sterilization activities in addition to standards ISO 11135 – 1 (EtO) / ISO 11137 – 1 (irradiation) and ISO 17665 – 1 (moist heat)

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

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MANAGEMENT SYSTEM CERTIFICATION QUESTIONNAIRE

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"/> Servicing | <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:

Please enclose a description sheet on 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? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Do you have a common management system for all sites? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Are similar activities carried out on each site? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Do several teams perform the same type of activity? (2x8, 3x8) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If yes, please fill in the table below:

shift (times)	Number of employees/shift



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GENERAL COMPANY AND MANAGEMENT SYSTEM INFORMATION

- 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

- What is your proposed time period for the certification audit (month and year)?

- Are you interested in other LNE services (training, tests, calibration...)?

No Yes, Specify: _____

- In the past 2 years, have you performed:

- Internal audit(s): Yes No

- Management review(s): Yes No



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 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 “sterilization”

Application for regulatory certification

- Medical devices concerned

Medical device (s) Trade name + category 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).

- Identification of main subcontractors (add 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

* enclose a copy of the certificates

- Sterilization

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)* + Annex IV.6 (verification of manufactured product)
	<input type="checkbox"/> Annex V (EC type examination)* + Annex VII (production quality assurance system) + Annex VII.5 (verification of manufactured product)
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

<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 I- Sterile**	<input type="checkbox"/> Annex II.3 (full quality assurance system without design examination)
Class I - with one or more measuring functions**	<input type="checkbox"/> Annex IV (EC verification)*
Class IIa	<input type="checkbox"/> Annex V (product quality assurance system)
Class IIa	<input type="checkbox"/> Annex VI (product quality assurance system)
Class IIb	<input type="checkbox"/> Annex II.3 (full quality assurance system without design examination)
Class IIb	<input type="checkbox"/> Annex IV (EC verification) + Annex III (EC type examination)*
Class IIb	<input type="checkbox"/> Annex V (product quality assurance system) + Annex III (EC type examination)*
Class IIb	<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*
Class III and active implantable medical devices	<input type="checkbox"/> Annex IV (EC verification) + Annex III (EC type examination)*
Class III and active implantable medical devices	<input type="checkbox"/> Annex V (product quality assurance system) + Annex III (EC type examination)*

* Annexes II.4 (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.

** For Class I sterile devices, the evaluation is limited to the aspects of manufacture concerned with securing and maintaining sterile condition. For Class I device with measuring function, the evaluation is limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.



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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: Please return this questionnaire to the contact person mentioned in page 1, or contact him or her for additional information.

Additional Services Available

If you are interested in any of these, please contact your Account Manager, who can provide the application form related to each standard.

Management Systems Certification– 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

Certification Packaging Field (Medicinal products)

- ISO 15378 – Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP)

- Training – ISO 13485, Directive 93/42/EEC, Risk Management, Internal Audit, Sterilization, others

- Testing – EMC, Safety, Mechanical, others

Questions?

Contact your Account Manager listed on page 1 or feel free to call our technical team at (301) 495-0477