Le progrès, une passion à partager

Organisme certificateur mandaté par
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CERTIFICATION RULES

NF MARK CONDOMS

AFNOR Certification identification no
NF 062
Ref. written by YQ/EG - LNE

Review no. 13 – May 2018
Approved by the Director-General of
AFNOR Certification:
on 19 February 2018

First applied: July 1985

Reference document:
GENERAL RULES OF THE NF MARK
Approved by the President of AFNOR on 23 April 2012

Founded in 1938, the NF mark is a collective certification mark, with the object of certifying the compliance of products with national, European and international standard documents covering them, and which may be complemented by additional specifications, in conditions defined by the certification reference standards. It is granted by AFNOR Certification and its network of partner bodies, making up the NF network.

The NF mark is voluntary product certification mark; it satisfies the requirements of the French Consumer Code, notably by associating the interested parties with the validation of the certification reference standards, by defining marking rules for certified products and by clear and transparent communication on the main characteristics certified.

The right to use the NF mark is granted on the basis of compliance with one (or more) standard(s) and more generally to the whole certification reference standard**,** for a product coming from an applicant and a designated design and/or manufacturing and/or marketing process. Attribution of the right to use cannot in any circumstances substitute the LNE's responsibility for that which is legally incumbent upon the company holding the right to use the NF mark.

The NF mark checks the characteristics covering the safety of persons and goods, the suitability for use and the durability of products, as well as any additional characteristics enabling products to be distinguished in the market.

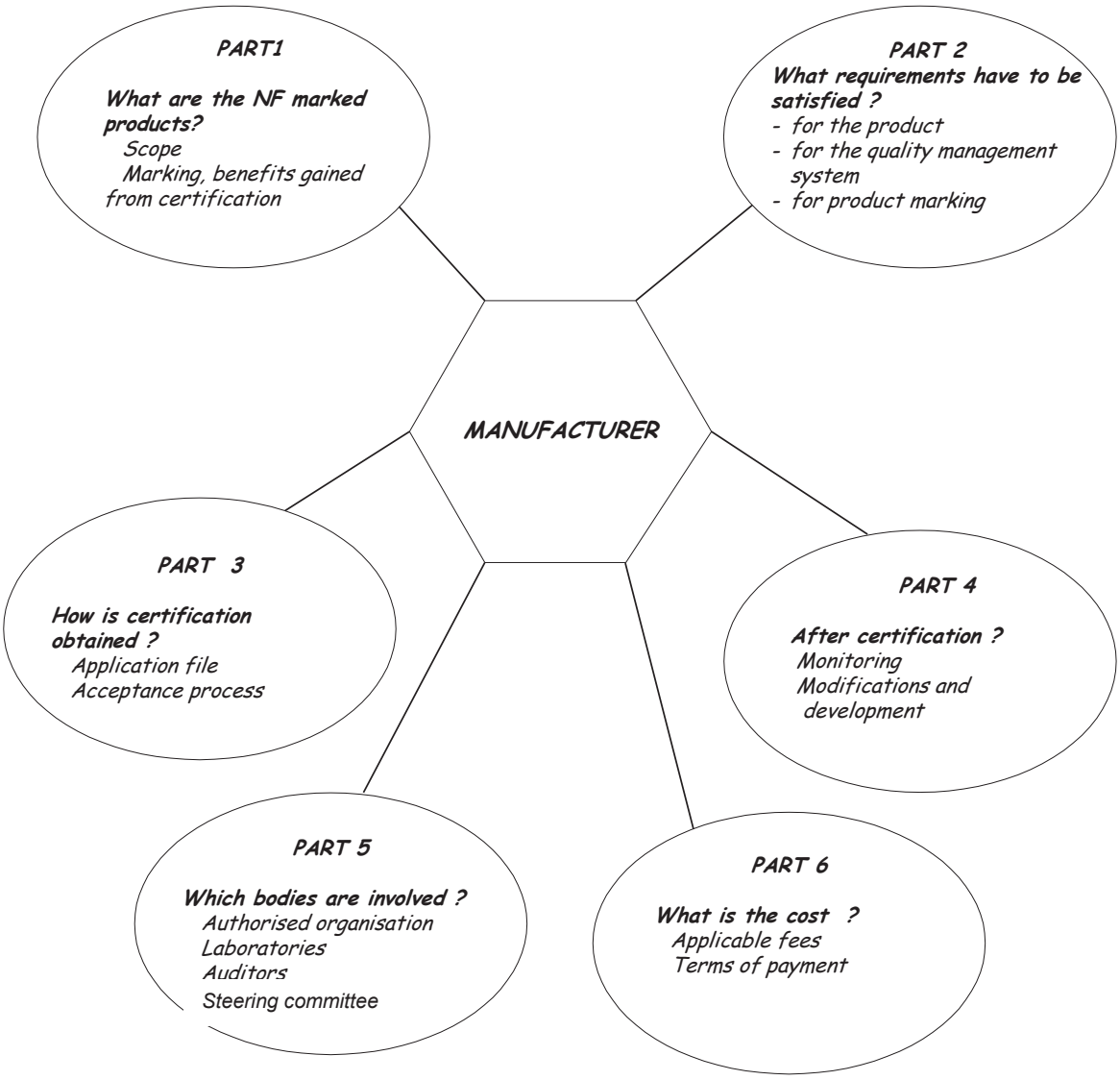
In accordance with the General Rules of the NF mark, AFNOR Certification entrusts the management of the NF mark - Condoms to the LNE, known as the mandated certifying body.

The LNE is responsible to AFNOR Certification for operations which are entrusted to it and are covered by a contract with AFNOR Certification.

Reminder*:
It is specified that all products or services must satisfy the regulations, independently of any certification application, concerning for example forgery, compliance and safety requirements, etc.

* Extract from the introduction of the NF X 50-067 standard: Creation of a certification reference standard for products or services or combinations of products and services

CERTIFICATION RULES



Who should you contact?
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The documents applicable in this certification are:

- the general rules of the NF mark laying down the general organisation and conditions of use of the mark,
- these certification rules which define, in part 2, the technical characteristics to be respected.

These certification rules were submitted for the approval of AFNOR Certification for acceptance in the NF certification system. They were approved by the Legal Representative of AFNOR Certification.

They cancel and replace all previous versions.

Hence the certification rules can be revised, in part or in whole, by the LNE after consultation with the interested parties.

UPDATING

Certification rules	Reason for update	Revision	Date
Part 1: Scope, Marking	- Added certified characteristics - Details concerning applicant/holder definitions	Rev 13	May 2018
Part 2: Quality requirements to be observed by the manufacturer	- Updated regulatory texts - Added an additional specification concerning Electric testing on 100% of condoms - Added clarifications on the application of aspects associated with the work environment of standard NF EN ISO 13485 - Added requirements in the event of subcontracting of all or part of product manufacturing - Added the applicant's/holder's commitment concerning the transmission to recipients of LNE test and audit reports	Rev 13	May 2018
Part 3: Obtaining certification	- Updated the forms included in the application dossier - Added details concerning the initial audit duration and sampling - Details concerning the decision and notification - Details concerning appeal against the decision	Rev 13	May 2018
Part 4: Surveillance process for certified products – Modifications and changes	- Added details concerning follow-up audit duration, along with tests and inspections - Details concerning the decision and notification - Details concerning appeal against the decision - Details concerning temporary interruption of production	Rev 13	May 2018
Part 5: Participating organisations	- Deleted the mark committee and added a steering committee	Rev 13	May 2018
Part 6: Applicable fees – Terms of payment		Rev 13	May 2018

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PART 1

SCOPE – NF MARKING

CONTENTS

Rev. 13 – May 2018

1.1. SCOPE

The products covered by these NF certification rules are:

- condoms, hereinafter referred to as "condoms";
- additional lubricants and other preparations intended to come into contact with condoms, hereinafter referred to as "additional lubricants".

The characteristics certified in the context of the NF-Condoms standard are as follows:

For condoms:
- No perforation
- Dimensions
- Burst pressure and volume
- Amount of lubricant compatible with a condom
- Packaging
- Packaging integrity

For lubricants:
- Lubricant compatibility with a reference condom, with burst pressure verification

It is the responsibility of the applicant/holder to ensure that the regulations applicable to its product are adhered to (e.g.: CE marking).

The applicant/holder is solely responsible for the compliance of its products; LNE inspections cannot replace the responsibilities of the applicant/holder.

1.2. DEFINITIONS

1.2.1 PRODUCTS

1.2.1.1. Condom

A condom model is defined by:
- the raw material (natural rubber latex);
- the dimensions (length, width, weight, thickness) and shape (see dimensioned drawing);
- the surface (smooth or textured);
- lubricated or not;
- with or without reservoir;
- the colour;
- the taste;
- the fragrance and/or a masking agent.

1.2.1.2. Batch of condoms

A batch is a certain number of condoms of the same design, colour, shape, size and latex formula, i.e. which conforms to the same product definition file, from the same production line, manufactured during the same continuous time period, using the same procedure, common batches of raw materials, the same equipment and packaged using the same lubricant and any other additive or hygiene product in the same sealed individual packaging and managed by the manufacturer via his quality system.

The number of condoms in an inspection batch should not exceed 150,000 units.

1.2.1.3. Lubricant

A lubricant is defined by:
- the designation (cream, emulsion, lotion, gel, oil);
- the formula (designation of components and their percentage according to the terms and conditions specified in the additional lubricant technical file).

1.2.1.4 Lubricant batch

A "batch" is a set of units packed with a defined lubricant, obtained from the same initial mass and subjected to a single series of manufacturing operations or a single sterilisation operation and managed by the manufacturer via his quality system. A batch may include packages of different sizes.

1.2.2. STAKEHOLDERS

1.2.2.1. Applicant/Holder

Artificial Person who manages and/or is responsible for compliance with all of the requirements defined in these certification rules of the NF Mark.
These requirements cover at least the following stages: design, manufacture, assembly, quality control, marking, packaging and putting on the market, and specify the critical points at each stage.
If the applicant/holder is not established in the European Community they should appoint an agent.

NB: the applicant must hold the CE certificate covering the products concerned by the application. If the distributor does not wish any specific reference to be made to the manufacturing site, a request must be submitted to LNE by the applicant. In this case, the production plant is not mentioned on the certificate.

1.2.2.2. Authorised agent

Artificial or Natural Person established in the European Economic Area (E.E.A.) who acts as representative of the applicant/holder outside the E.E.A. and has a written mandate from the latter meaning that he can act in its name in the NF mark certification process according to the provisions of the certification regulations.

The authorised agent may also be the distributor, or the importer of the certified products, in which case their different functions are clearly identified.

1.2.2.3. Distributor

Artificial Person distributing the applicant's/holder's or its authorised agent's products who does not act upon the product or its packaging. If the distributor puts NF products on the market independently of the agent, he takes responsibility for the verification of the conformity with the NF certification rules and the applicable standards.

The types of distributor may be as follows:

- distributors who distribute the product under the trademark of the holder. In this case, no action is to be taken with regard to the NF Mark.
- distributors who distribute the product with a change in trademark The applicant/holder and the distributor must apply to maintain the right to use.

If the distributor does not want to make an explicit reference to the manufacturing site, an application must be submitted to LNE by the distributor. In this case, the production plant is not mentioned on the certificate.

Depending on the operations performed by the applicant/holder or distributor, the audited sites and the audit period within the framework of the initial certification or surveillance are defined case by case.

1.3. NF MARK

The NF Mark is materialised by the monogram below:

The marking conditions for products, packaging and technical and commercial documents are defined in Part 2

The graphics rules for the NF mark are available on request from the LNE.

The purpose of the marking rules is to guide the holder in how to meet the regulations and the requirements of the NF certification. The general rules of the NF mark specify the conditions of use, of validity and the penalties in the event of abusive use of the NF mark.

Without prejudice of the sanctions laid down in the General Rules of the NF mark, any incorrect announcement of the certified features and any fraudulent use of the NF logo expose the holder to lawsuits for fraud and/or misleading advertising.

1.4. CERTIFIED PRODUCTS

A list of the certified products is available via the certificate search engine on the www.lne.fr, in the section entitled "Certification", "Certified companies/products", "Product certificates issued by the LNE".

On request, the LNE can provide information regarding the validity of a given certificate.

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PART 2

REQUIREMENTS TO BE MET BY THE APPLICANT/HOLDER

CONTENTS

Rev. 13 – May 2018

2.1. – REQUIREMENTS CONCERNING PRODUCTS

2.1.1. REFERENCE STANDARDS

NF S 97-034 (December 2007) - Additional lubricants and medicinal and non-medicinal preparations, intended or likely to be placed in contact with condoms.

NF EN ISO 4074 (December 2015) Condoms in natural rubber latex – Requirements and test methods

NOTE: In the framework of the NF mark, the test under point 6.2 of standard NF EN ISO 4074 (September 2002) – Test on batch of condoms subjected to ageing – is maintained as part of the batch-by-batch inspection and in the inspection plan set up by the manufacturer for the NF Mark-Condoms.

2.1.2. FURTHER SPECIFICATIONS

- Number of inspection batches: the number of condoms in an inspection batch shall not exceed 150 000 units.

- The in-process inspection by “Electric Testing” must be performed on 100% of condoms produced.

- Defects during tests: if an empty foil is detected, it is counted as a visible defect and a new foil is sampled in order to comply with the sampling methodology required for the testing.

- When the foil is opened for the bursting tests (before and after), if the LNE detects a visible defect (stained condom, permanent folds in the film, etc.), the condom in question is tested in that condition and, so that the customer is informed thereof, the defect is noted down in the test report and a photo, taken before the destructive test, attached.

2.1.3. SPECIFICATIONS CONCERNING THICKNESS

a) Classification
Condoms covered by standard NF EN ISO 4074 are classed in 3 categories for thickness:

Category	Claim	Thickness
A	very fine (*)	th $\leq$ 55 µm
B	fine	55 µm < th $\leq$ 80 µm
C	thick	th > 80 µm

(*) or any other claim referring to "fine" with a superlative.

The distinction between the 3 classes is made on the basis of the average thickness obtained at the mid-point of the condom.

b) Measurement
The measurement is made by weighting at the mid-point as per Appendix F of standard NF EN ISO 4074 on 13 condom specimens.

2.2. REQUIREMENTS CONCERNING THE QUALITY MANAGEMENT SYSTEM

2.2.1. GENERAL REQUIREMENTS

For the products concerned by application of this mark, the manufacturer's quality system must conform to the specifications of standard NF EN ISO 13485 : 2016 Quality management systems – Requirements, with the exception of requirements concerning “Design and development” (chapter 7.3 of the standard) which shall not apply.

However, because the version 2012 of the standard NF EN ISO 13485 is still applicable, a transitional period has been set under the Condoms NF Mark.

That transitional period is defined until 28th February 2019.

Thus, during that period, the manufacturer's quality system can conform to the version 2012 or the version 2016 of the standard NF EN ISO 13485. Since 1st March 2019, the manufacturer's quality system must conform to the version 2016 of the standard NF EN ISO 13485.

2.2.2. SPECIFIC QUALITY REQUIREMENTS

2.2.2.1. Work environment - Para. 6.4 of standard NF EN ISO 13485

To comply with Chapter 6.4 a), people who come into direct contact with condoms must wear gloves and masks.

To comply with Chapter 6.4 b), measures must be taken to mark out "clean" zones in which staff are likely to come into direct contact with non-packaged condoms (zones for Electric Testing and foiling in particular) and to monitor staff and environmental hygiene conditions, so as to avoid any product contamination.

2.2.2.2. Verification of product purchased - Para. 7.4.3. of standard NF EN ISO 13485

The manufacturer must check the quality of raw materials used in the manufacture of products for which he holds the right to use the NF Mark.

For example, defined and regular inspections on reception or certificate of conformity with suppliers' technical specifications or general specifications.

Records must be made of inspections carried out indicating the acceptance criteria and decisions taken in the event of nonconformity.

Should all or part of product manufacturing be subcontracted, the manufacturer shall:
- assess and select subcontractors according to their ability to meet the requirements of the sub-order, including quality system requirements and any quality assurance-specific requirements;
- define the type and scope of the control exerted by the manufacturer on its subcontractors.
This latter must be determined by the type of product ordered from the subcontractor, from this product’s impact on the end product and, where applicable, on the quality audit reports and/or records concerning the aptitudes and performance previously demonstrated by the subcontractor;
- draft, update and keep records of acceptable subcontractor quality.

Orders must clearly describe the ordered product (technical characteristics, quantities, deadlines, etc.), make reference to the tender specifications and stipulate, if necessary, the requirement for a certificate of analysis.

NB: The holder, requesting the subcontracting, is responsible for the compliance of the NF certified products as per the provisions of the certification rules, considering that in the event of nonconformity, the necessary verifications are performed by the manufacturer or subcontracting applicant, depending on the quality provisions adopted for this subcontracting.

2.2.2.3. Identification and traceability - Para. 7.5.9. of standard NF EN ISO 13485

The manufacturer must prepare instructions for identifying the product with marking that conforms to the requirements of Para. 2.3. below.

Traceability is a requirement of the NF mark. Consequently, the measures defined in standard NF EN ISO 13485 (2012) concerning unique identification of the product must be taken into account.

This identification must guarantee traceability and allow the history of the product to be traced.

2.2.2.4. Preservation of the product - Para. 7.5.11. of standard NF EN ISO 13485

Storage
The manufacturer shall use designated storage areas or premises to avoid the damaging or the deterioration of the product pending its use or delivery.

To detect any deterioration, the condition of the product in stock shall be evaluated at appropriate and defined intervals.

Packaging
The manufacturer must manage the packaging, packing and marking processes, insofar as necessary to ensure compliance with specified requirements.

2.2.2.5. Product monitoring and measurement - Para. 8.2.6. of standard NF EN ISO 13485

The inspection plan set up must guarantee the conformity of the products with the specifications of Para. 2.1. and must specify how often the inspections are to take place.

Records must be made of inspections carried out indicating the acceptance criteria and decisions taken in the event of nonconformity.

2.2.2.6. Control of nonconforming product - Para. 8.3. of standard NF EN ISO 13485

The manufacturer must ensure that products not conforming to requirements pertaining thereto are identified and controlled so that they cannot be unintentionally used or supplied.

Inspections and associated responsibilities and powers for processing nonconforming products must be defined in a written procedure.

The manufacturer must process a nonconforming NF-marked product in one of the following ways:

- by conducting actions to eliminate to the nonconformity;
- by authorising its use, release or acceptance with a waiver, in which case prior agreement must be obtained from the LNE;
- by conducting actions to prevent its use (scrapping for example).

Records of the nature of nonconformities and all follow-up actions undertaken, including waivers obtained, must be kept.

When a nonconforming product is corrected, it must be verified again to demonstrate conformity with the requirements.

When a nonconforming product is detected after delivery or after it has been put into use, the manufacturer must take suitable action to inhibit the real or potential effects of the nonconformity.

Records indicating complaints made against certified products and their processing must be made and kept.

2.2.2.7. Minimum requirements for inspecting and testing condoms

Minimum inspection and testing
Within the framework of the NF Mark-Condoms, the inspection plan implemented must at least include testing and inspection for conformity, as explained below, on the finished product.

Inspection and testing as per internal specifications, standard NF EN ISO 4074 and Para. 2.1 above:

- Dimensions;
- Bursting volume and pressure;
- Tensile strength (if there is a reinforced condom claim);
- Absence of perforation;
- Quantity of lubricant;
- Packaging;
- Packaging integrity.

The finished product is defined as the condom completely packaged in an individual pack.

The means to be implemented to carry out this inspection and testing are left up to the manufacturer's initiative as long as the requirements concerning the inspection batch and the AQLs (Acceptable Quality Levels) are complied with.

Acceptance and rejection conditions
Sampling must be carried out on one batch of finished products (completely packaged).

The sampling plans stipulated by standard NF EN ISO 4074 must be applied.

The manufacturer may use simple, double or multiple sampling plans, according to the terms and conditions described in the NF ISO 2859-1 standard.

The manufacturer may employ reduced inspection or may need to use increased inspection in accordance with the rules for inspection changes, given in the NF ISO 2859-1 standard.

The manufacturer undertakes to destroy nonconforming batches (the conditions of this destruction are specified in the quality control plan. The action taken is entered, case by case, in the inspection register).

The manufacturer keeps records of the individual measurements obtained at each test required on each batch.

2.2.2.8. Minimum requirements for inspecting and testing lubricants

Minimum inspection and testing
Within the framework of the NF Mark-Condoms, the inspection plan implemented must at least include testing and inspection for conformity, as explained below, on the finished product.

Inspection and testing as per the NF S 97-034 standard:

- Lubricant compatibility with a reference condom by verification of burst pressure

Inspection of raw materials
The manufacturer must carry out or have carried out an inspection of the raw materials used in the manufacture of each product batch for which he holds the right to use the NF Mark.

Inspections during manufacturing
Inspections must be carried out during manufacturing and cover at least the following points:

- final analysis of the product before packaging, for verification of manufacturing specifications,
- microbiological analysis of the product before packaging,
- if the final packaging is carried out on another site, an acceptance inspection of the product in bulk must be carried out beforehand.

The type of inspections and acceptance criteria are to be defined by the manufacturer.

Inspection of finished products
Inspection of each batch is carried out on samples taken according to written procedures prepared by the manufacturer which must make it possible to ensure the representativeness of the sample.

Inspections carried out must make it possible to verify compliance with manufacturing specifications, especially with respect to the microbiological cleanliness and composition.

When the finished-product is not packaged immediately, the maximum storage periods and the storage conditions must be specified and complied with.

The inspections must necessarily cover the following points:

Microbiological inspection:
Justification of compliance with the following specifications:

Micro-organisms	Concentration tolerated
Mesophilic Aerobic Bacteria	N/g < 1000
Staphylococcus aureus	Absence on 25 g
Pseudomonas aeruginosa	Absence
Candida albicans	Absence

Physical-chemical verifications:
To be defined by the manufacturer (for example: pH, density, etc.)

Another sample is taken and preserved, until the batch expiration date.

The inspections carried out must be recorded and the records must include at least the following data:
a) the identification and the relevant quantity,
b) the batch number making it possible to ensure product traceability,
c) the references to the corresponding specifications and to the inspection procedures,
d) the results of the analyses,
e) the inspection dates,
f) the identification of the operators,
g) the acceptance or refusal decision, and the responsible party's dated signature.

2.3. REQUIREMENTS CONCERNING MARKING

Marking is an integral part of the certification of a product.

Beyond the identification of a certified product and its traceability, the marking of a product with the NF logo ensures better protection of the users and enables holders to be protected against unauthorised use and forgery.

Without prejudice of the sanctions laid down in the General Rules of the NF mark, any incorrect announcement of the certified features and any fraudulent use of the NF logo expose the holder to lawsuits for fraud and/or misleading advertising.

Copying of and marking with the logos of AFNOR, AFNOR Certification, and the LNE is strictly forbidden without prior authorisation from these bodies.

The holder undertakes to respect the graphics rules of the NF mark.

The NF certified product must bear a designation and identification distinct from non-NF certified products. The holder must only use the NF logo to distinguish NF certified products, without risk of any possible confusion with other products, particularly with non-NF certified products.

It is recommended that the holder submit all of the documents relating to the NF mark to the LNE beforehand.

REMINDER:
Article R 433-2 of the French Consumer Code stipulates that:
"When reference is made to certification in advertising, labelling or presentation of any product or service or in associated commercial documents of any kind, the following information must always be brought to the consumer's or user's attention:

- *the name or corporate name of the certifying body or the collective certification mark,*
- *the denomination of the certification reference standard used,*
- *the modalities according to which the certification reference standard can be consulted or obtained."*

2.3.1. Marking regarding condoms

2.3.1.1. Packaging labelling as per requirements of standard NF EN ISO 4074

NB: since it is not possible to mark the products themselves, the marking requirements concern the individual packaging (or foils), the sales packaging and the information leaflet

A) Individual packaging

Each individual packaging must bear the indications stipulated in Para. 11.2.2 of standard NF EN ISO 4074 along with the following additional indications:

a) the trade reference accepted by the NF Mark is such as defined in the certificate;
b) the batch number;

It is recommended to affix the NF logo on the individual packaging according to the template below:

The English version "certified by LNE" is available from the LNE

B) Sales packaging

Each sales packaging must bear the indications stipulated in Para. 15.2.4 of standard NF EN ISO 4074.

Moreover, each sales packaging must feature the NF logo, in a permanent, visible and durable manner, in line with the requirements of the graphics rules and with the template below (the English version "certified by LNE" is available from the LNE) and in line with the specific standards and regulations in force.

The following indications must feature alongside the NF logo:

- a code to ensure product traceability;
- the commercial name of the product appearing on the certificate;

The English version "certified by LNE" is available from the LNE.

2.3.1.2. Consumer information leaflet

The minimum indications concerning the use of the condom must feature on the packaging intended for the consumer and/or internal leaflet, as per the provisions of Para. 15.2.4. of standard NF EN ISO 4074.
Together with: "Non-opaque individual packaging should not be stored outside the opaque sales packaging".

Note: for “delayed-effect” condoms which contain a drug such as benzocaine, the outer packaging must clearly mention any possible allergy risks.

It is recommended to affix the NF logo on the information leaflet according to the template below:

The English version "certified by LNE" is available from the LNE.

2.3.1.3. Information relative to condoms sold in automatic distributors

Insofar as it is not possible to see all information included on the pack intended for the consumer on condoms sold in automatic distributors, information shall be put at retailers’ disposal on the automatic distributor, stating the following:

- trade reference and mark accepted for the NF Mark,
- number of condoms contained in each pack,
- NF logo as per the following template:

The English version "certified by LNE" is available from the LNE.

2.3.2. Marking concerning additional lubricants

A) Tube/bottle

The tube/bottle must feature the following indications, written in French:

- the name or corporate name and address of the manufacturer, and, when applicable, the name and address of the manufacturer's authorised agent or importer doing business in the European Economic Area;
- the identification of the lubricant and content of the pack (volume or weight) and the qualitative and quantitative information concerning the substances whose presence is set forth in the descriptive information, the advertising or the product denomination (excluding the composition);
- the batch number or the reference enabling product traceability;
- the expiry date, expressed in month and year;

It is recommended to affix the NF logo on the tube/bottle according to the template below:

The English version "certified by LNE" is available from the LNE.

B) Sales packaging

The pack (or the instructions accompanying the packaging with respect to points e), f) and g) must include the following information, written in French:

a) the name or corporate name and address of the manufacturer, and, when applicable, the name and address of the manufacturer's agent or importer doing business in the European Economic Space;

b) the identification of the lubricant and content of the pack (volume or weight) and the qualitative and quantitative information concerning the substances whose presence is set forth in the descriptive information, the advertising or the product denomination (excluding the composition).

c) the batch number or the reference enabling product traceability;

d) the expiry date , expressed in month and year;

e) special storage and/or handling conditions;

f) special instructions for use;

g) warnings and/or precautions which must be taken;

h) the intended use of the product and, especially, the possibility of it being put in contact with condoms;

Moreover, each sales packaging must feature the NF logo, in a permanent, visible and durable manner, in line with the requirements of the graphics rules (see template below, the English version "certified by LNE" is available from the LNE) and in line with the specific standards and regulations in force.

The English version "certified by LNE" is available from the LNE.

2.3.3. Marking on documentation (technical and commercial documents, posters, advertising, websites, etc.)

References to the NF mark in documents (order confirmations, invoices, delivery slips, advertising leaflets, catalogues, etc.) must be made in a way that avoids any risk of confusing certified products with others.

The NF Mark must be reproduced on documents and advertising in compliance with the requirements defined in Para. 2.3.1:

The English version "certified by LNE" is available from the LNE.

Prior to publication, it is recommended that the holder submit any sales document bearing the Mark, including modifications of said documents, to the LNE.

The holder must send, on request from the LNE, any document in which reference is made, directly or indirectly, to the NF mark.

2.4. APPLICANT'S/HOLDER'S COMMITMENTS

The applicant/holder endeavours generally to give the LNE the means to proceed in operations necessary to the good process of the evaluation and the follow-up of its file and in particular to:

- constantly meet the requirements defined by these certification rules, and to implement the necessary changes in the timeframes set by the LNE in the event that the certification rules change,
- give the representatives authorised by the LNE the information and working documents necessary to the good progress of the evaluation;
- only communicate information which the applicant/holder assures is loyal and sincere;
- designate a supervisor as the LNE's special contact person;
- designate the recipients, within the company, who are to receive the LNE test and audit reports and to inform the LNE of any changes to be taken into consideration in the event of a change of recipient within the company, or of email address;
- introduce to the LNE's authorised representatives the personnel assigned to the different missions;

- give its personnel all the instructions required so that it collaborates with the authorised representatives and accepts to participate in whatever interview;

- provide authorised the LNE representatives with means of access and transportation within the sites and buildings being audited, including sites of sub-contractors if necessary;

- inform authorised the LNE representatives of the health & safety instructions and measures applicable to the sites and buildings being audited and its personnel and put at their disposal whatever relevant equipment;

- pay the LNE the amounts due for evaluation, in accordance with the financial conditions defined and accepted by the applicant/holder

- authorise the presence of an observer who is required to respect confidentiality. The LNE may be required to call for this observer as per the standards or agreements of which it is a signatory. The applicant/holder is systematically informed of the presence of this observer by the LNE prior to the audit.

- take the necessary measures if non-conformities are noted, within the timeframe stipulated by the LNE,

- return to the audit manager the duly filled out non-conformity sheets, within 3 weeks from the last day of the audit.

- implement the actions required to enable the certificate to be granted within 11 months of the initial audit. Once this deadline has passed, a new audit will have to take place before certification.

- send to the mark laboratory the samples taken in the conditions defined in parts 3 and 4.

It is also incumbent on the certificate holder to:

- affix the NF mark on only the products covered by the certificates issued by the LNE and which conform to the applicable requirements;

- reserve the commercial name of the product for only the products covered by the certificates issued by the LNE and which conform to the applicable requirements;

- inform the LNE beforehand of any modification to the product and any information likely to affect conformance to the requirements of these rules, the assessment methods being defined in part 4,

- provide the LNE with any data or information necessary to draw up and maintain the certificate;

- keep a record of all complaints the holder is aware of concerning the conformity of (a) product(s) to certification requirements, and to provide the LNE with these records upon request, and
    - to take any appropriate action regarding these complaints and imperfections noted in the products which impact their conformity to the certification requirements.
    - to document the actions taken.

- to stop making any reference to the certification of the products concerned and to stop using all of the means of communication making reference thereto in the event of suspension, reduction, withdrawal or refusal of renewal of the certificate,

- to authorise follow-up authorisations to be carried out during the period of validity of the certificate, based on the frequency specified in part 4, in addition to any other duly justified supplementary evaluation.

- to make declarations on the certifications in line with the scope of the certificate,

- not to use the certification granted by the LNE in a way which could damage the LNE, nor make a statement on the certification of its products which the LNE could consider as misleading or non-authorised;

- to reproduce the certificates in their entirety, including appendices in the event of provision to a third party.

Le progrès, une passion à partager

Organisme certificateur mandaté par
AFNOR Certification
1, rue Gaston Boissier
75724 PARIS Cedex 15
Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37
www.lne.fr

CERTIFICATION RULES

NF MARK CONDOMS

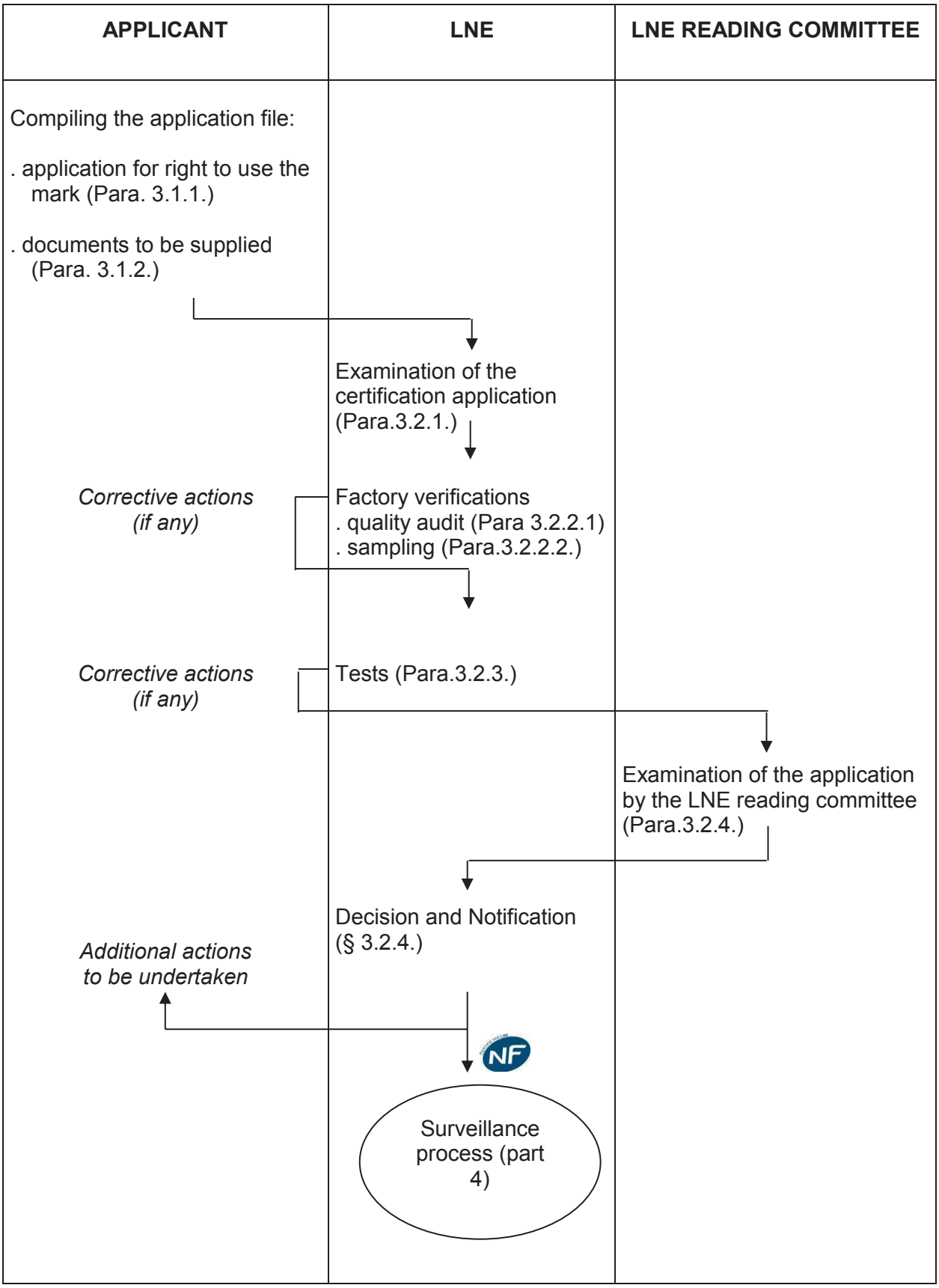
PART 3

OBTAINING CERTIFICATION

CONTENTS

Rev. 13 – May 2018

PROCESS FOR OBTAINING CERTIFICATION



Before making the application, the applicant must be sure to meet, at the time of the application, the conditions defined in these Certification Rules (reference standard), especially those in Part 2, regarding his product and sites in question.

He must undertake to comply with said conditions throughout the period of using the NF mark.

If he fails to respect these rules, the applicant/holder exposes himself to the interruption or suspension of the processing of his file. Notably, it is not possible in any circumstances to make reference to the NF mark before obtaining the right to use the NF mark, or to present forged products for certification.

3.1. COMPILING THE APPLICATION FILE

Any company manufacturing one or more products covered by this application of the NF mark can request the right to use the mark. A request of this kind is known in this document as an "application" and the person formulating it as the "applicant".

3.1.1. APPLICATION FOR THE RIGHT TO USE THE NF MARK

Any manufacturer wishing to obtain NF certification for a product it manufactures must first read carefully the certification rules for the Mark and declare his acceptance of them.

The application is drawn up on the manufacturer's letterhead paper as shown in the template (form no. 1a) and must be sent to the LNE.

It must specify the models of products presented during the certification application:
- Natural rubber latex condoms
- Lubricants

The applicant undertakes to back his application up with a file containing, for each factory that manufactures the products for which certification is being sought, the documents or information specified in Para. 3.1.2. below.

The application can only be received if the inspections described in part 2 of these regulations have been carried out beforehand on at least 3 batches of each model.

All the documents must be written in French or English.

The application must be accompanied by full payment of the corresponding fees determined at the processing of the file and the initial audit.

If the applicant is not from a country within the European Economic Area, he must present his application jointly with an agent set up within the European Economic Area, duly accredited and responsible for all the production for which NF certification is being sought and marketed on French soil.
He is known as the "agent".

Prior to affixing the NF Mark, any modification made to the range defined during application must be pointed out to the LNE which will decide whether or not additional tests need to be carried out.

3.1.2. DOCUMENTS TO BE SUPPLIED

3.1.2.1 Condoms

When applying for certification regarding condoms, the application must send to the LNE all of the items listed below, which shall make up the application file:

- Standard certification application letter (form no. 1a) written on the manufacturer's letterhead paper as shown in the enclosed template (with its appendix co-signed and the associated mandate co-signed) (as shown in form no. 1d) for applications from outside the European Economic Area);

- List of reference(s) of the condoms concerned by the certification application (form no. 1b);

- Distributor’s commitment (form no. 1e) if the mark owner is not the applicant;

- Copy of the valid CE marking certificate in the applicant’s/holder’s name (together with the Appendix listing the covered products), which must indicate the references of the condoms concerned by the application;

- Description of quality management measures in place:
    - General organisation chart (positions and workforce)
    - Quality manual and/or plan(s) if possible (if these documents are not distributed outside the site, they must always be made available to the auditor during the audit).
    - - Description of the manufacturing sequence and the inspection plan used (indicating measurements and tests carried out and their frequency).
    - Description of the various processes with definition of input, output, activities taken into account in each process (in reference to NF IN ISO 13485 - 2016 standard)
    - Certificate of conformity of the quality management system (if appropriate)

- A technical file comprising the technical datasheet for condoms (form no. 1c), drawn up for each model presented, together with all of the documents required in form no. 1c.

All the documents must be written in French or English.

FORM no. 1a (natural latex condoms)

CERTIFICATION APPLICATION
(to be typed on the applicant's letterhead paper)

LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS
Pôle Certification Plurisectorielle
1, rue Gaston Boissier
75724 PARIS Cedex 15

Purpose: Application for the right to use the Mark NF-CONDOMS

Dear Sir,

I the undersigned (name and position)……
representing the company (identification of the company - head office)……
request the LNE to carry out the verifications required for obtaining the right to use the NF Mark for the condoms specified in the enclosed table, complying with the specifications of **part 2 para. 2.1.** of the certification rules.

This application concerns the condoms produced in the plant located: (**company identification and full address of the factory)** ……
of the model defined on the technical datasheet enclosed.

I declare that I am familiar with the reference standards, the general rules of the NF Mark and the NF062 certification rules (especially paragraph 2.4. concerning my commitments) and its corresponding appendices, and I generally undertake to comply with them throughout the period of use of the NF Mark.

I attest that these products satisfy the regulatory requirements applicable to them and I undertake not to present forged products for certification.

Date
Stamp and signature of applicant

APPENDIX TO THE CERTIFICATION APPLICATION (1)

.... Furthermore, I authorise the company (2)……..
represented by Mr (name and capacity)..... ..... ……..

who accepts the terms of the attached mandate, to act on my behalf on the French territory for all matters relating to the use of the NF Mark.

I undertake to notify the LNE immediately if I appoint a new agent to replace the agent named above.

Date
Stamp and signature
of the agent's representative (3)

Stamp and signature
of the applicant's representative (3)

(1) This appendix is only to be completed by applicants located outside the European Economic Area. . It must be accompanied by a co-signed mandate (see sample form 1d)
(2) The designation of the representing company must include: company name, legal form, head-office and Companies Register number.
(3) The signatures of the applicant and his agent must be preceded respectively by the hand-written words "Proxy agreed" and "Acceptance of proxy agreed".

FORM no. 1b (natural latex condoms)
(to be typed on the applicant's letterhead paper)

REFERENCE OF THE CONDOM(S) COVERED BY THE CERTIFICATION APPLICATION

TRADEMARK	TRADE REFERENCE OF THE MODEL(S) (2)	BATCH CODIFICATION (1)

Applicant’s name

Date

Stamp and signature

(1) In reference to the definitions in part 1, Para. 1.2
(2) In reference to the definitions of part 1, Para. 3.1.1

FORM no. 1c (natural latex condoms)
(to be typed on the applicant's letterhead paper)

TECHNICAL DATASHEET FOR CONDOMS
(one sheet should be prepared for each model presented)

1. INFORMATION CONCERNING THE SITE(S) IN QUESTION

- Name of applicant's company:
  - Applicant's address:
  - Contact:
  - Telephone:
  - Fax:
  - E-mail:

Contact details of the correspondents to whom LNE test and audit reports should be emailed:

Contact's name	Position	e-mail	Audit report	Test report

Billing address (if different from the applicant company's address), with commitment if different from the applicant

_____

_____

Location of the various manufacturing steps

	Address and contacts of the site responsible for each stage (*)
Design	
Manufacture (details if manufacture is outsourced)	
Assembly	
Final check	
Marking	
Packaging	
Storage	

Any aspect not covered by the applicant is subject to a contract defining the respective responsibilities with its provider

- Invoices concerning the NF Mark should be sent to (*) (with undertaking if different from the applicant):

_____

- Number of sites (overall, concerned by the certified products and production/inspection-laboratory breakdown) and associated routines (shift work, workforce and shift times):

- Surface area of the site(s) (overall and offices/production/laboratory breakdown):

- Is/are the site(s) a group subsidiary? Are there subsidiaries? (If Yes, specify):

- Description of the site production means:

- Description of the site inspection means:

Trademark:

Trademark owner*:

List of distributors, in charge of marketing, named on the packaging

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2. DATA ABOUT THE MODEL OF CONDOM

2.1. Commercial data

- Trademark:

- Owner of the trademark(*):
  NOTE: if the owner is not the applicant, this document must be filled in regarding the basic trademark and reference, along with form no. 1e and a maintenance application for the others – see part 4, Para. 4.2.3

- Other trademarks/references applied to the model:
  NOTE: if several trademarks or references exist for the same model, fill in this document for the basic trademark and reference, along with form no. 1e and a maintenance application for the others – see part 4, Para. 4.2.3

- List of distributors, people responsible for the market launch, whose name appears on the package(*):

- No. and date of registration with the INPI (*Institut National de la Propriété Industrielle*) of the trademark(s):

2.2. Description of the model

(*) Indicate the company name, address, contact person, phone number and e-mail address if different from the applicant

(*) Indicate the company name, address, contact person, phone number and e-mail address if different from the applicant

2.2.1 Specific points

- Raw material:
- Smooth or textured surface:
- lubricated or not:
- Colour:
- Taste:
- Flavor:

2.2.2 Nominal dimensions of the model (announced by the manufacturer)

Length (mm):
Width (mm):
Distance for measurement of width (with diagram):
Weight (g):
Thickness (µ):
Form:

3. LIST OF DOCUMENTS TO ATTACH TO FORM NO. 1c

3.1. Documents concerning the site(s)

- The map(s) for accessing the different sites described in Para. 1 above;

3.2. Documents concerning the condom model

- Technical datasheet of the condom's components;

- Results of design validation tests carried out by the manufacturer on the product concerned by the application,

- Detailed photos and/or drawing showing the condom model's dimensions;

- Description of the final inspection bench;

- All of the draft marking for the individual packaging (foil);

- All of the draft marking for the sales packaging;

- The draft user's leaflet (when applicable);

- Copy of the filing to the INPI (*Institut National de la Propriété Industrielle*) of the trademark(s), or the certificate concerning the national or international registration of the trade reference(s);

Applicant’s name
Date
Stamp and signature
(and initialled on all of the pages of form 1c)

FORM no. 1d (natural latex condoms)

EXAMPLE OF A MANDATE
(to be drawn up on the applicant/agent's letterhead paper)

List of information to be supplied:

- Corporate name: _____
- Address: _____
- Country: _____
- Telephone: _____ Fax: _____
- SIRET No.: _____ NAF code: _____
- Name and profession of the legal representative: _____
- Name and profession of the correspondent (if different): _____
- VAT ID number: _____
- Email address of contact person: _____
- Email address of the Company: _____
- Website: _____

Identification of the roles of the authorised agent to be included in the mandate between applicant/holder and agent

Applicant/Holder: .....

Authorised agent:.....

Minimum requirements which must be shown in the mandate:

- assignments and associated responsibilities
- financial aspects (invoicing relating to the NF mark)
- complaints
- certifying body contact

Mandate:

The mandate should be mentioned in the applicant/holder's quality system.

A copy of the mandate in French or English should be attached to the co-signed certification application.

Compliance with the mandate arrangements is checked during audits.

Date of the initial mandate

Signatures of the representative of the agent and the applicant

FORM No. 1e

DISTRIBUTOR'S COMMITMENT
(to be drawn up on the distributor's letterhead)

I the undersigned,_____

acting as_____

for the company:_____

do hereby acknowledge that by placing my trademark _____ on the following model(s) covered by this certification application, I am required to assume the related responsibilities.

Reference(s) of the condom(s) covered by the application	
Mark	Commercial reference

In particular, I certify that I possess exclusive rights concerning this mark and this(these) commercial reference(s), by submission performed in accordance with applicable industrial property legislation.

I also undertake to market the aforementioned model(s) for which this application has been drawn up, without making any changes whatsoever.

I have attached to this commitment the statement concerning the national or international registration of the aforementioned commercial reference(s).

Drawn up in on

Signature

Distributor's stamp:

Manufacturer's or representative's
stamp and signature:

3.1.2.2 Lubricants

When applying for certification regarding lubricants, the application must send to the LNE all of the items listed below, which shall make up the application file:

- Standard acceptance application letter (form no. 2a) written on the manufacturer's letterhead paper as shown in the enclosed template (with its appendix co-signed and the associated mandate co-signed) (as shown in form no. 2d) for applications from outside the European Economic Area);

- List of reference(s) of the lubricants subject to the certification application (form no. 2b);

- Distributor’s commitment (form no. 1e) if the mark owner is not the applicant;

- Copy of the valid CE marking certificate in the applicant’s/holder’s name (together with the Appendix listing the covered products), which must indicate the references of the condoms concerned by the application;

- Description of quality management measures in place:
    - General organisation chart (positions and workforce)
    - Quality manual and/or plan(s) if possible (if these documents are not distributed outside the site, they must always be made available to the auditor during the audit).
    - - Description of the manufacturing sequence and the inspection plan used (indicating measurements and tests carried out and their frequency).
    - Description of the various processes with definition of input, output, activities taken into account in each process (in reference to NF IN ISO 13485 - 2016 standard)
    - Certificate of conformity of the quality management system (if appropriate)

- A technical file comprising the technical datasheet for lubricants (form no. 2c), drawn up for each model presented, together with all of the documents required in the form.

All the documents must be written in French or English.

FORM no. 2a (lubricants)

CERTIFICATION APPLICATION FORM
(to be typed on the applicant's letterhead paper)

LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS
Pôle Certification Plurisectorielle
1, rue Gaston Boissier
75724 PARIS Cedex 15

Purpose: Application for the right to use the Mark NF-CONDOMS

Dear Sir,

I the undersigned (name and position) ……
representing the company (identification of the company - head office) ……
request the LNE to carry out the verifications required for obtaining the right to use the NF Mark for the lubricants specified in the enclosed table, complying with the specifications of **part 2 para.** 2.1 of the certification rules.

This Application concerns the lubricants produced in the plant located: (**company identification and full address of the factory)** ……
of the model defined on the technical datasheet enclosed.

I declare that I am familiar with the reference standards, the general rules of the NF Mark and the NF062 certification rules (especially paragraph 2.4. concerning my commitments) and its corresponding appendices, and I generally undertake to comply with them throughout the period of use of the NF Mark.

I attest that these products satisfy the regulatory requirements applicable to them and I undertake not to present forged products for certification.

Date
Stamp and signature of applicant

APPENDIX TO THE CERTIFICATION APPLICATION (1)

.... Furthermore, I authorise the company (2)
represented by Mr (name and capacity)..... .....

who accepts the terms of the attached mandate, to act on my behalf on the French territory for all matters relating to the use of the NF Mark.

I undertake to notify the LNE immediately if I appoint a new agent to replace the agent named above.

Date
Stamp and signature
of the agent's representative (3)

Stamp and signature
of the applicant's representative (3)

(1) This appendix is only to be completed by applicants located outside the European Economic Area. It must be accompanied by a co-signed mandate (see sample form 1d)
(2) The designation of the representing company must include: company name, legal form, head-office and Companies Register number.
(3) The signatures of the applicant and his agent must be preceded respectively by the hand-written words "Proxy agreed" and "Acceptance of proxy agreed".

FORM no. 2b (lubricants)
(to be typed on the applicant's letterhead paper)

REFERENCE OF THE LUBRICANTS COVERED BY THE CERTIFICATION APPLICATION

TRADEMARK	TRADE REFERENCE OF THE MODEL(S) (2)	BATCH CODIFICATION (1)

Applicant’s name

Date

Stamp and signature

(1) In reference to the definitions in part 1, Para. 1.2
(2) In reference to the definitions in part 1, Para. 3.1.1

FORM no. 2c (lubricants)
(to be typed on the applicant's letterhead paper)

TECHNICAL DATASHEET CONCERNING LUBRICANTS
(one sheet shall be prepared for each model presented)

PAGE 1 / 3

1. INFORMATION CONCERNING THE SITE(S) IN QUESTION

- Applicant's company:
  - Applicant's address
  - Contact:
  - Phone:
  - Fax:
  - E-mail:

Name(s) and address(es) of the correspondent(s) to whom the LNE test and audit reports should be emailed:

Contact's name	Position	e-mail	Audit report	Test report

Billing address (if different from the applicant company's address), with commitment if different from the applicant

Location of the various manufacturing steps

	Address and contacts of the site responsible for each stage (*)
Design	
Manufacture (details if manufacture is outsourced)	
Assembly	
Final inspection	
Marking	
Packaging	
Storage	

Any aspect not covered by the applicant is subject to a contract defining the respective responsibilities with its provider

- Invoices concerning the NF Mark should be sent to (*) (with undertaking if different from the applicant):

- Staff of the site(s) (overall, concerned by the certified products and production/inspection-laboratory breakdown) and associated routines (shift work, workforce and shift times):

- Surface area of the site(s) (overall and offices/production/laboratory breakdown):

- Is/are the site(s) a group subsidiary? Are there subsidiaries? (If Yes, specify):

- Description of the site production resources:

- Description of the site inspection resources:

Trademark:

Trademark owner*:

List of distributors, in charge of marketing, named on the packaging

(*) Indicate the company name, address, contact person, phone number and e-mail address if different from the applicant

2. INFORMATION CONCERNING THE LUBRICANT

2.1. Commercial data

- Trademark:

- Owner of the trademark(*):
  NOTE: if the owner is not the applicant, this document must be filled in regarding the basic trademark and reference, along with form no. 1e and a maintenance application for the others – see Appendix 1 and 2 below

- Other trademarks/references applied to the model:
  NOTE: if several marks or references exist for the same model, fill in this document for the basic mark and trade reference, along with form no. 1e and a maintenance application for the others – see Appendices 1 and 2 – see part 4, Para. 4.2.3

- List of distributors, people responsible for the market launch, whose name appears on the package(*):

- No. and date of registration with the INPI (*Institut National de la Propriété Industrielle*) of the trademark(s):

2.2. Description of the model

- Complete formula of product including identification of substances present and the quantitative composition. The chemical substances are designated by their scientific name; substances of plant or animal origin are designated by their usual denomination; the colourings may also be designated by their Colour Index number or their EEC number,

For pharmaceutical specialities (in the sense of the 65/65/EEC Directive):

- Copy of the authorisation to market the product,

For products not coming under the 65/65/EEC Directive:

- Copy of the CE declaration of conformity referred to in Annex VII of the 93/42/EEC Directive.

(*) Indicate the company name, address, contact person, phone number and e-mail address if different from the applicant

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3. LIST OF DOCUMENTS TO ATTACH TO FORM NO. 1c

3.1. Documents concerning the site(s)

- The map(s) for accessing the different sites described in Para. 1 above;

3.2. Documents concerning the lubricant model

- Technical datasheet of the lubricant's components;

- Results of design validation tests carried out by the manufacturer on the product concerned by the application,

- Description of the final inspection bench;

- All of the draft marking for the individual packaging;

- All of the draft marking for the sales packaging;

- The draft user's leaflet (when applicable);

- Copy of the filing to the INPI (*Institut National de la Propriété Industrielle*) of the trademark(s), or the certificate concerning the national or international registration of the trade reference(s);

Applicant’s name
Date
Stamp and signature
(and initialled on all of the pages of form 1c)

FORM no. 2d (lubricants)

EXAMPLE OF A MANDATE
(to be drawn up on the applicant/agent's letterhead paper)

List of information to be supplied:

- Corporate name: _____
- Address: _____
- Country: _____
- Telephone: _____ Fax: _____
- SIRET No.: _____ NAF code: _____
- Name and profession of the legal representative: _____
- Name and profession of the correspondent (if different): _____
- VAT ID number: _____
- Email address of contact person: _____
- Email address of the Company: _____
- Website: _____

Identification of the roles of the authorised agent to be included in the mandate between applicant/holder and agent

Applicant/Holder: .....

Authorised agent:.....

Minimum requirements which must be shown in the mandate:

- assignments and associated responsibilities
- financial aspects (invoicing relating to the NF mark)
- complaints
- certifying body contact

Mandate:

The mandate should be mentioned in the applicant/holder's quality system.

A copy of the mandate in French or English should be attached to the co-signed certification application.

Compliance with the mandate arrangements is checked during audits.

Date of the initial mandate

Signatures of the representative of the agent and the applicant

3.2. INITIAL ASSESSMENT PROCESS

3.2.1. EXAMINATION OF THE CERTIFICATION APPLICATION

The application and enclosed file sent to the LNE are examined before factory verifications and tests are carried out.

Upon receiving the application, the LNE checks that:
- all the requested documents are enclosed in the application file according to Para. 3.1.2.,
- the elements in the file comply with the requirements of the certification rules.
- the fees have been paid,

The LNE checks that it has all the means for responding to the application and may request additional information required for the admissibility of the file when this is incomplete.

Once the application is admissible, the LNE organises the inspections, and informs the applicant about the organisation methods (auditor, duration of the audit, audited sites, laboratories, sampled products, etc.) and, if applicable, the due date for the additional items.

The checks carried out in connection with the NF mark are as follows:
- audits so as to be able to cover the various participants in the design, manufacture, assembly, quality control, marking and packaging of the products (see Para. 3.2.2).
- tests on the products (see 3.2.3),

The test samples are taken during the initial audit and/or specified in each RC sent by the applicant to the designated laboratory.

3.2.2. AUDIT

Examination of the application includes an initial audit of the factory where the products presented in the application dossier are manufactured. It also includes, if applicable, an audit of the various sites participating and described in the certification application, on the basis of the same standard. It is conducted by auditors qualified by the LNE who have given an undertaking to observe professional secrecy.

The language of the audit is French or English. If this is not the case, it is up to the company being audited to make available an interpreter to the auditor. In this case the duration of the audit may be increased (prior agreement with the company).

The NF auditor must have at his disposal all the resources necessary (documents, premises, installations, facilities) to perform his assignment, including competent people to carry it out.

3.2.2.1. Quality audit

This audit is conducted according to the general principles defined in standard ISO 19011 for conducting a quality audit. In particular, the scope of the audit and details of the procedure are specified in an audit plan sent to the company before the audit

The auditor(s):

- Conduct(s) a quality audit with the purpose of verifying the existence and effective implementation of the quality management system set up by the manufacturer and its conformity with the quality requirements in Part 2 of these regulations.

.

- Check(s) that the verifications required in Part 2 have been carried out on at least 3 batches of each model in order to verify the application of frequencies, operating procedures and criteria defined by NF certification rules and ensure(s) that compliance testing on products covered by the certification application is conducted in their presence. It is preferable to carry out these tests on the model sampled for tests in the mark laboratory.

  NOTE: test results obtained during the audit do not prejudge results obtained by the mark laboratory.

- Take(s) the samples required for the initial tests.
- Examine(s), if necessary, the application of the contract with the agent and/or the various sites participating and described in the certification request.

The duration of the on-site audit is 3-day audit for condom manufacturing sites and 2-day audit for lubricant manufacturing sites.

The duration of the on-site audit for packaging and/or final inspection sites is of 0.5-day audit.

The duration of the audit can be adapted to the sites to be audited (with prior consent of the applicant).

With the company's agreement, the auditors can take a copy of any document they consider necessary.

At the end of the closing meeting, the lead auditor prepares an audit report which he gives to the applicant, drawing special attention to the effectiveness of the quality system set up, the strong points, the points to be improved and a commented report of non-conformities. It also includes the report of tests carried out during the audit and the sampling sheet.

If one or more non-compliant points have been noted, the applicant completes the headings of the non-compliance sheets and sends them within the time agreed with the lead auditor to the latter for assessment.

The complete report is emailed by the LNE to the correspondent(s) designated by the applicant, with, if applicable, a copy to the agent.

3.2.2.2. Sampling and testing

3.2.2.2.1. Taking of condom samples from the place of manufacture and tests

The manufacturer must make available to the lead auditor all models of the product covered by the certification application needed for the sample.

Auditors collect the samples needed for testing that have been validated by the manufacturer's inspection plan.

Packaged samples (individual packaging) required for the inspections and tests are to be taken as follows:

- 6 large per batch (one large (144) = 12 x 12 condoms) per model (covered by the certification application), on at least 3 batches for the tests concerning conformity to the specifications of part 2 herein.

If several variants of a given condom model are produced (taste, fragrance, colour, etc.), packaged samples (individual packaging) required for inspections and tests, are collected as follows:

- 6 large (one large (144) = 12 x 12 condoms) on 3 batches of the model and on 1 batch of each variant, for tests concerning conformity to the specifications of part 2 herein.

If the condoms are not lubricated and packed on the production site, the samples are taken from the packing site.

The samples taken are marked by the auditors with a distinctive sign used to authenticate them later, and must be accompanied by information allowing the samples taken to be identified.

They are sent within 15 days by the manufacturer, and under his responsibility, to the independent laboratory (see Part 5 of these Certification Rules) tasked with carrying out the tests, accompanied by the sample sheet, unless the auditors decide to take charge of them.

Laboratories entitled to use the mark must verify each specification of the standard, using a single sampling plan, except for volume and bursting pressure specifications, for which verification tests are carried out using a double sampling plan as described in standard NF ISO 2859-1 (April 2000) for inspection level GI and an AQL of 1.5.

Note: in the event of a claim regarding extremely fine thickness on the packaging, the LNE shall verify the stated claim in accordance with Para. 2.1.3 of part 2 of the certification rules.

3.2.2.2.2. Taking of a sample for comparison of manufacturer's results with those of the reference laboratory

Additional samples are taken for comparison of the bursting test results.

In order to ensure that the manufacturer's inspection test findings are valid, a sampling of 80 non-packaged and non-lubricated condoms from the same batch intended to bear the NF Mark is taken:

- the 40 condoms will be subjected to bursting tests by the manufacturer in the presence of the auditor, according to the same arrangements as those stipulated in his quality plan. The findings, recorded in writing by the manufacturer, are incorporated in the audit report;
- The other 40 condoms are taken away by the auditor for the bursting test in the mark laboratory. They may also be sent by post together with the sampling sheet within 15 days by the manufacturer, and under his responsibility, to the mark laboratory (see part 5 herein) tasked with performing the tests.

The findings are submitted to the manufacturer within 3 months of the audit date.

In the event of non-conforming results obtained as a part of batch by batch inspection (cf. Part 4, Para. 4.1.4) the results obtained by the manufacturer and the mark laboratory for bursting tests are analysed by the mandated body in order to search for the possible reasons of the non-conformities, in connection with the mark laboratory and the manufacturer.

In any case, the non-conforming batch must be destroyed.

3.2.2.2.3. Samples of lubricants taken on the place of manufacturing

A sample of a total mass of around 300 g from a batch of packaged samples required for the inspections and tests is taken during the audit.

When the products are not packaged at the place of manufacture, the samples are taken at the place where they are packaged.

The samples necessary for the inspections and tests may also be taken in commercial outlets.

The samples are checked in relation to the specifications described in standard NF S 97-034.

The samples taken are marked by the auditors with a distinctive sign used to authenticate them later, and must be accompanied by information allowing the manufacturing batch to be identified.

They are sent within 15 days by the manufacturer, and under his responsibility, to the mark laboratory (see Part 5 of these Certification Rules) tasked with carrying out the tests, unless the auditors decide to take charge of them.

3.2.3. TESTS

The tests to be carried out by the independent laboratory concern verification of the specifications defined in Part 2 of these Certification Rules.

NOTE: In the event of condoms claiming a category A thickness, the thickness declared by the applicant for a new model is inspected during the tests performed for the certification application.

Tests are carried out on samples taken during the audit or sent by the manufacturer.

A test report is drawn up for the tests and sent by the LNE to the correspondent(s) designated by the applicant, with a copy where applicable to the agent.

In case of non compliance, the manufacturer shall inform the LNE of its analysis of the causes and corrective actions taken while specifying the time taken.

3.2.4. DECISION AND NOTIFICATION

On the basis of the results obtained during examination of the application and the recommendation of the LNE reading committee, the LNE notifies the applicant of one of the following decisions:

a) Certification agreed
   This decision may be accompanied by suspensive conditions which define the conditions to be met by the applicant before the certificate is awarded

b) Certification refused.

The certification decision must take effect no more than one year after the initial audit.

By virtue of the certification decision notified by the LNE, AFNOR Certification grants the right to use the NF mark.

If the right to use the NF Mark is awarded, the beneficiary is known as the "holder". Maintaining this right is subject to the results of the verifications defined in Part 4.

The exercise of the right to use the NF Mark is strictly limited to the products for which it was awarded, in other words the duly defined products from the duly defined factories, and manufactured under the conditions set out in these Regulations.

Once the right to use the NF Mark has been granted, all of the batches must be inspected by the LNE before marketing, which may only take place once compliant findings have been obtained and the LNE agrees in writing.

3.2.5. APPEAL AGAINST A DECISION

The applicant may appeal against any decision taken. The procedure is set out in Article 11 of the General Rules of the NF Mark. This appeal is notified by recorded delivery letter within 15 business days.

The LNE firstly proceeds with the re-examination of the file in view of the factors justifying this challenge. It notifies confirmation of the decision or the new decision to the applicant within 30 working days.

Should the applicant wish to maintain its challenge, an appeal may be made by the applicant or certification beneficiary against the decision of the LNE.

Explanations for this appeal, which does not have a suspensory effect, must be given. It is lodged by sending a recorded delivery letter within 15 working days.

It is examined by the LNE upon receipt.

The appeal is presented to the LNE’s Certification and Preservation of Impartiality Committee that issues its conclusions after examination.

The company is notified of the final decision by the LNE.

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Organisme certificateur mandaté par
AFNOR Certification
1, rue Gaston Boissier
75724 PARIS Cedex 15
Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37
www.lne.fr

CERTIFICATION RULES

NF MARK CONDOMS

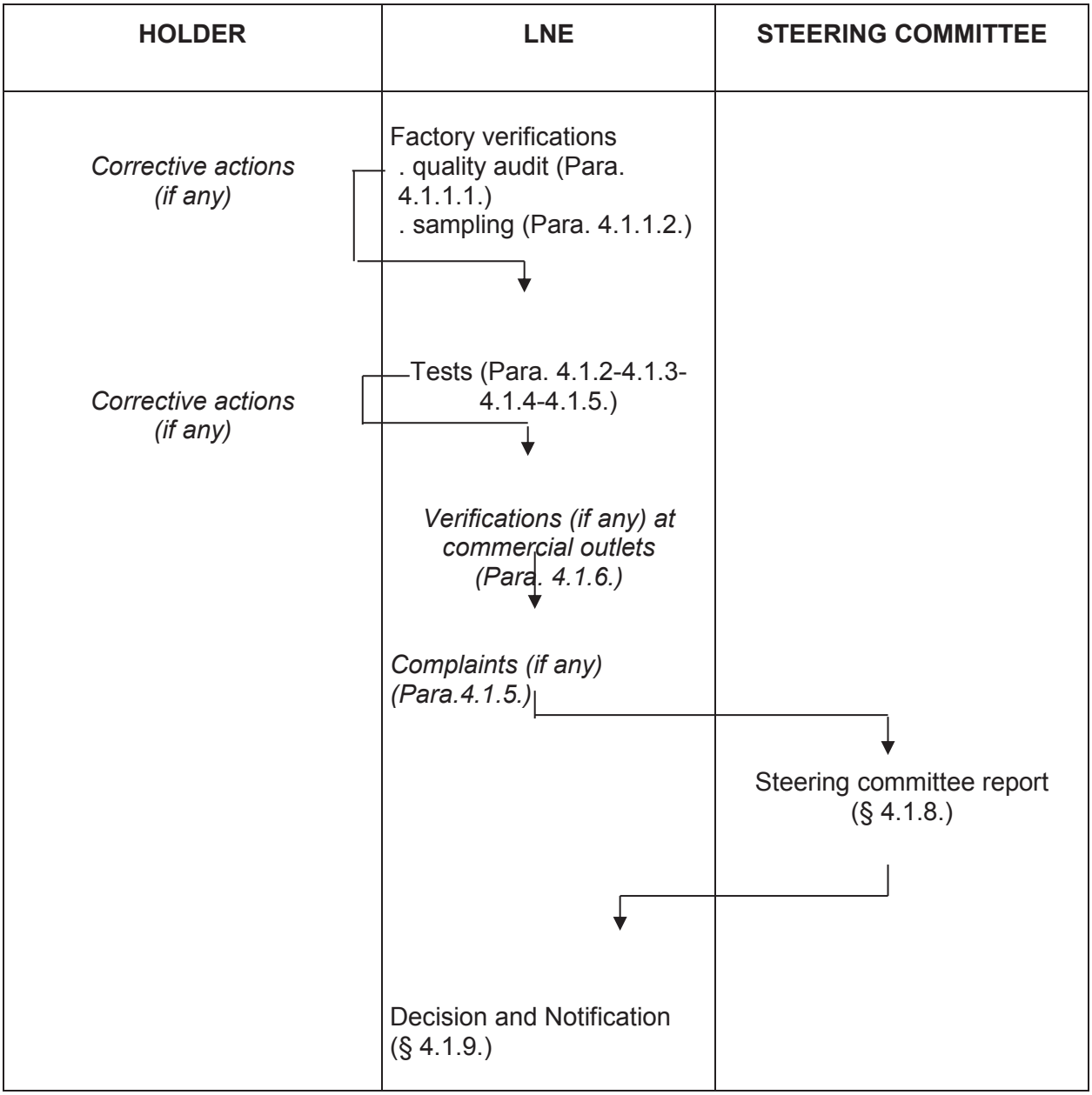
PART 4

CERTIFIED PRODUCT SURVEILLANCE PROCESS MODIFICATIONS AND CHANGES

CONTENTS

Rev. 13 - May 2018

SURVEILLANCE PROCESS



Throughout the certification period, the holder must:

- comply with the requirements defined and marking arrangements described in part 2,

- systematically inform the LNE of any change to one of the certified product's characteristics, and/or to its organisation which is likely to affect the certification:

    - modifications concerning the holder (Para. 4.2.1.)
    - transfer of production site (Para. 4.2.2.)
    - modification of the accepted product, new products (Para. 4.2.3.)
    - Temporary stoppage of production (Para. 4.2.4.)
    - definitive stoppage of production or surrendering the right of use (Para. 4.2.5.)

In addition, the LNE reserves the right to carry out any checks it deems necessary following:

- a modification concerning the certified product or the quality organisation of the various intervening sites and described in the original certification application file.
- complaints, challenges, disputes of which it has been informed and relating to the use of the NF Mark.

4.1. CERTIFIED PRODUCT SURVEILLANCE PROCESS

The LNE organises surveillance of certified products.

The first follow-up audit occurs no later than six months after the certification decision.

The purpose of this surveillance is to monitor compliance by the manufacturer with the requirements of these rules.

The surveillance methods depend on the decisions made as a result of previous inspections.

4.1.1. AUDIT

At least one audit per year per manufacturing site is conducted (main site and possibly secondary sites tasked with the final inspection and/or packaging).

The LNE defines, on a case-by-case basis, which sites are to be audited in addition and the associated frequency among different intervening sites and described in the original certification application.

The duration of the audit can be adapted:

- depending on the sites to be audited in accordance with the requirements of Para. 3.2.1 (with prior consent of the holder)
- if a holder has several authorised agents,

The examinations carried out concern primarily any modifications made since the previous audit that affect manufacturing, inspection methods or organisation of the quality management system.

This quality audit is conducted according to the general principles defined in standard ISO 19011 for conducting a quality audit. In particular, the scope of the audit and details of the procedure are specified in an audit plan sent to the company before the audit.

During each audit, products are sampled for bursting tests at the mark laboratory (see Para. 4.1.1.2.).

During the audit, the auditor has conformity tests carried out in his presence on accepted products, in order to verify the conditions under which inspections are performed by the manufacturer. It is preferable to carry out these tests on the model sampled for tests in the mark laboratory.

NOTE: test results obtained during the audit do not prejudge results obtained by the mark laboratory.

With the manufacturer's agreement, the auditor can take a copy of any document he considers necessary.

4.1.1.1. Quality audit

Verification of the quality management measures must include, at each audit, verification of compliance with the specific requirements of the NF Mark (Para. 2.2.2. Part 2) and the following chapters of standard NF EN ISO 13485 (2012), through the processes defined by the manufacturer:

7.5.3. Identification and traceability,
7.5.5. Preservation of product,
7.6. Control of measuring and monitoring devices,
8.2.4. Measurement and monitoring of product,
8.3. Non-compliant product control,
8.5.2. Corrective actions,

The other processes (and chapters of the standard) are verified during the various annual follow-up audits (in alternation).

The audit duration for a condom manufacturing site (audit and writing of the report on site) depends on the number of agents/holders for whom the audit is performed:

- 1 authorised agent: 1.5 days on-site
- 1 to 2 agents: 2 days on-site
- 3 to 4 agents: 2.5 days on-site
- 4 to 5 agents: 3 days on-site

The audit of a lubricant manufacturing site lasts 1 day on-site.

The audit of a condom and lubricant manufacturing site lasts 2 days on-site.

The audit of a packaging and/or final inspection site lasts 0.5 days on-site.

Audit duration may be adapted to the sites to be audited (subject to prior agreement by the applicant).

With the company’s consent, the auditors may make copies of any documents they deem necessary.

At the end of the closing meeting, the lead auditor prepares an audit report which he gives to the holder, drawing special attention to the effectiveness of the quality system set up, the strong points, the points to be improved and a commented report of non-conformities. It also

includes the report of tests carried out during the audit and the sampling sheet (see Para. 4.1.1.2).

If one or more non-compliant points have been noted, the holder completes the headings of the non-compliance sheets and sends them within the time agreed with the lead auditor to the latter for assessment.

The complete report is emailed by the LNE to the correspondent(s) designated by the holder, with, if applicable, a copy to the agent.

4.1.1.2. Taking of a sample of condoms for comparison of the manufacturer's test results with those of the reference laboratory

Additional samples are taken for comparison of the bursting test results.

In order to ensure that the manufacturer's inspection test findings are valid, a sampling of 80 non-packaged and non-lubricated condoms from the same batch intended to bear the NF Mark is taken:

- the 40 condoms will be tested for bursting resistance by the manufacturer in the presence of the auditor, according to the same arrangements as those stipulated in his quality plan. The findings, recorded in writing by the manufacturer, are incorporated in the audit report.
- The other 40 condoms are taken away by the auditor for the bursting test in the mark laboratory. They may also be sent by post together with the sampling sheet within 15 days by the manufacturer, and under his responsibility, to the mark laboratory (see part 5 herein) tasked with performing the tests.

The findings are submitted to the manufacturer within 3 months of the audit date.

In event of non-conforming results obtained as a part of batch by batch inspection (see Para. 4.1.4) the results obtained by the manufacturer and the mark laboratory for bursting tests are analysed by the mandated body in order to search for the possible reasons of the non-conformities, in connection with the mark laboratory and the manufacturer.

4.1.1.3. Samples of lubricants taken on the place of manufacturing

A sample of a total mass of around 300 g from a batch of packaged samples required for the inspections and tests is taken during the audit.

When the products are not packaged at the place of manufacture, the samples are taken at the place where they are packaged.

The samples necessary for the inspections and tests may also be taken in commercial outlets.
They are marked by the auditor with a distinctive sign used to authenticate them later and sent within 15 days by the manufacturer, and under his responsibility, to the Mark laboratory tasked with carrying out the tests, together with the sampling sheet, unless the auditors decide to take charge of them.

4.1.2. TESTS

The tests to be carried out by the mark laboratory concern verification of the specifications defined in Part 2 of these Certification Rules. Tests are carried out on samples taken during the audit or sent by the manufacturer (see batch-by-batch inspection)

A test report is drawn up for the samples collected and sent by the LNE to the correspondent(s) designated by the holder with copy, where applicable, to the agent.

IMPORTANT NOTE:
Should the LNE detect non-compliant results, the manufacturer shall apply the provisions stated in part 2, Para. 2.2.2 (Non-compliant product control) to inform its customers and recall the products.

The manufacturer shall inform the LNE of its analysis of the causes and corrective actions taken as a result of the observed non-conformity, while specifying the time taken.

4.1.3. BATCH-BY-BATCH INSPECTION OF CONDOMS

Given the risks that using a defective condom is likely to entail in terms of public health, the afore-mentioned verifications are to be supplemented by a batch-by-batch inspection performed at the mark laboratory, after unitary packaging.

The sampling is carried out under the manufacturer's responsibility and, if necessary, following instructions from the LNE.

Quantity to be sampled:
6 large (one large (144) = 12 x 12 condoms) per model and per batch, for testing conformity with standard NF EN ISO 4074.

Depending on the circumstances they are either carried out:
- at the manufacturer's premises before dispatch, in individual or collective packaging
- at the packer's premises.

The mark laboratory verifies each specification of the standard, using a multiple sampling plan, except for volume and bursting pressure specifications, for which verification tests are carried out using a multiple sampling plan.

The corresponding batch may only be marketed after notification from the LNE to the manufacturer or his agent.

IMPORTANT NOTE:

In the event of a non-conformity being discovered, the LNE informs the manufacturer or its agent that the batch must not be sold and that it must be destroyed (see Para. 2.2.2.7).

Penalties in the framework of the batch-by-batch inspection

a) the decision to perform an additional audit shall be made:
- if 2 noncompliant batches are recorded in 1 year for manufacturers producing 0 to 39 batches in 12 months;
- if 5% of noncompliant batches are recorded in 1 year for a manufacturer producing 40 batches or more in 12 months;

b) the suspension of a reference shall be pronounced regardless of the number of batches manufactured:
if 3 noncompliant batches are recorded out of 5 batches in the same reference received consecutively at the LNE for testing.
If necessary, the LNE shall consult the bureau members to ask their opinion.

4.1.4. INSPECTION OF LUBRICANTS

The samples are checked in relation to the specifications of standard NF S 97-034.

IMPORTANT NOTE:
If non-conforming results are detected by the LNE, the manufacturer must apply the measures stipulated in Part 2, Para. 2.2.2. (Control of non-conforming product) to inform its customers and call in the products.

4.1.5. VERIFICATIONS AT COMMERCIAL OUTLETS

In addition to the previous measures, the LNE may request verifications to be carried out in the distribution circuit. The results are sent to the holder concerned.

4.1.6. COMPLAINTS

If there are user complaints, the inspections may include sampling or tests at the places where accepted products are marketed (in this case the holder is invited to arrange for representation during the sampling and tests).

4.1.7. STEERING COMMITTEE SUMMARY

A summary of all the inspections carried out is presented by the LNE at least once a year to the Steering Committee.

The documents issued to the steering committee members must be presented in anonymous form.

4.1.8. DECISION AND NOTIFICATION

On the basis of the inspection results and any recommendations from the LNE reading committee, the LNE notifies the holder of one of the following decisions:

a) Maintaining the certification with a possible request for corrective action

b) Maintenance of certification, with formal notification to stop any infringements observed, within a given time period, possibly accompanied by increased inspections, tests and audits (which may be unannounced).

c) Suspension of the certification (suspension has a maximum duration of 6 months and is renewable once only. After this, withdrawal of the certification is pronounced.)

d) Withdrawal of certification.

For sanctions b), c) and d), the fees for additional verifications are charged to the holder, regardless of their results. The decisions are enforceable as from the date of notification.

If there is a serious breach of the Certification Rules, the LNE may, as precautionary measure and after confirmation of the breach, make any of the decisions listed above. The decisions are reported to the Steering Committee.

Certificates are renewed by periods of 3 years

4.1.9. APPEAL AGAINST A DECISION

The holder may appeal against the decision taken, as per Article 11 of the General Rules of the NF Mark. This appeal is notified within 15 working days by recorded delivery letter with acknowledgement of receipt.

The LNE firstly proceeds with the re-examination of the file in view of the factors justifying this challenge. It notifies confirmation of the decision or the new decision to the applicant within 30 working days.

Should the applicant wish to maintain its challenge, an appeal may be made by the applicant or certification beneficiary against the decision of the LNE.

Explanations for this appeal, which does not have a suspensory effect, must be given. It is lodged by sending a recorded delivery letter with acknowledgement of receipt within 15 working days.

It is examined by the LNE upon receipt.

The appeal is presented to the Certification and Impartiality Preservation Committee of the LNE, which proposes its conclusions after examination.

The final decision is notified to the Company by the LNE.

4.2. MODIFICATION AND CHANGES TO COMPANY ORGANISATION OR CERTIFIED PRODUCT

4.2.1. MODIFICATION CONCERNING THE HOLDER

In the case of merger, liquidation or acquisition of the holder's company, any right to use the Mark that it might exercise shall cease automatically (see article 4 of the General Rules of the NF Mark). The holder must inform the LNE without delay of any decision likely to result at a later stage either in a modification of the company's legal status or a change in the company name.

Non-compliance with this obligation observed by the LNE can lead to suspension or withdrawal of the right to use the NF mark.

The LNE is empowered, after consulting the LNE Reading Committee if necessary, to examine the means by which any new application might be certified.

In case of merger or consolidation involving only a change of company name, without modification of the product, manufacturing process, material and human resources, quality organisation and methods of control, the NF certificate may be updated upon receipt of written notification of the new company name on the company's letterhead paper.

4.2.2. MODIFICATION CONCERNING SITES COVERED BY THE CERTIFICATION

Before total or partial transfer of an activity described in the application file, the holder shall inform the LNE in writing of any new arrangements envisaged. From the transfer date, the holder must cease to mention the mark until the LNE makes a decision.

The LNE's decision comes after the audit of the new site and, where appropriate, presentation to the LNE reading committee (maintained certification or examination of a new application, with reduced or complete tests).

4.2.3. MODIFICATION OF THE ACCEPTED PRODUCT - NEW PRODUCTS

NF certified products shall conform to the technical file that was submitted with the application for acceptance, and shall take into account any observation made when the right to use the Mark was granted.

Consequently, any modification (including modifications concerning the manufacturing and inspection means and the quality management system that could have a determining effect on production conformity) that the holder wishes to make to accepted products must also be communicated to the LNE in writing. In addition, the holder shall notify the corresponding "distributor" certificates, if appropriate.

An application for a new type and/or model takes the form of an application for extension of the right to use the NF Mark.

The modification is examined on the basis of the table below and cannot be implemented until the LNE has given its agreement. The LNE must inform the holder of the examination arrangements (acceptance, preliminary inspections or referral to the LNE reading committee) within 15 days.

The samples required for carrying out tests are sent by the applicant and under his responsibility, to the mark laboratory charged with carrying out the tests. They must be marked in a way that allows later authentication and be accompanied by information allowing the material batches used for their manufacture to be identified.

Type of change	Application to be sent to the LNE	Examination of the application	Extension notification conditions
Change of authorised agent	Application according to form 1a-b-c-d or 2a-b-c-d part 3	Complete procedure. The procedure can be simplified in view of the conclusions of the last audit, the last test results in the case where the product covered by the application is identical to the previous certified model	In view of the test and audit findings (without consulting the mark committee if there is no particular problem)
Appointment of an additional authorised agent	Application according to form 1a-b-c-d or 2a-b-c-d part 3	Complete procedure. The procedure can be simplified in view of the conclusions of the last audit, the last test results in the case where the production and inspection conditions are unchanged with respect to the previously accepted model	In view of the test and audit findings (without consulting the mark committee if there is no particular problem)
Application for extension for a new product (product already certified for this type)	Application according to form 1a-b-c-d or 2a-b-c-d part 3	By file, with tests on 1 batch	In view of the test findings (without consulting the mark committee if there is no particular problem)
Application for extension for a new product (no product already certified for this type)	Application according to form 1a-b-c-d or 2a-b-c-d part 3	By file, with tests and audits	In view of the test and audit findings (without consulting the mark committee if there is no particular problem)
Modification of an accepted product	Application according to form 1a-b-c-d or 2a-b-c-d part 3, description of changes to product and inspection plan	By file, with tests if necessary	In view of the test findings (without consulting the mark committee if there is no particular problem)
New trade reference of a model already admitted to the NF Mark or in the process of being admitted	Maintenance application according to Appendix 1 and 2 of this part, together with all of the documents required in Appendix 1	By file	Without consulting the mark committee
Other case	Report changes	On case by case basis	On case by case basis

In the event that the product covered by the request for change has received approval to maintain the right to use the NF mark, the application shall include a new maintenance application, jointly signed by the holder and distributor.

4.2.4. TEMPORARY STOPPAGE OF PRODUCTION

The holder shall keep the LNE informed of any temporary stoppage of production of an admitted product if this is to last at least six months.

The holder must apply for a provisional suspension of the right to use the mark (maximum duration of 1 year) insofar as he no longer has any products bearing the NF mark in stock. After this period, the right of use is withdrawn.

Once the suspension timeframe has passed, the holder must notify the LNE if manufacturing is resumed and an inspection audit and tests are performed before the products are marketed under the NF Mark.

The holder must inform the LNE immediately of any temporary stoppage of production of an admitted product.

Should there be no production of a trade reference for more than 1 year, the right of use of the NF Mark for this reference is suspended if, after a warning from the LNE, the reference has not been imported and inspected within the following 6 months.
If, following this 6-month period after LNE warning, the reference has not been inspected, the right to use the NF Mark for this reference is withdrawn.

4.2.5. DEFINITIVE STOPPAGE OF PRODUCTION OR SURRENDER OF THE RIGHT OF USE

If the holder ceases production of an accepted product definitively or if he surrenders the right to use the Mark, he must inform the LNE, indicating the time he considers necessary for depletion of the remaining stock of products bearing the Mark. The LNE lays down the conditions under which this stock can be depleted, after seeking the LNE reading committee's opinion if necessary.

The certificate issued by the LNE remains valid as long as it remains with the holder of NF-marked product stock, as surveillance checks on certified products are maintained.

APPENDIX 1 of part 4

FORM
APPLICATION FOR MAINTENANCE OF THE RIGHT TO USE
(to be drawn up on the applicant's letterhead paper)

Monsieur le Directeur Général du
LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS
Pôle Certification Plurisectorielle
1, rue Gaston Boissier
75724 PARIS Cedex 15

Purpose: Application for maintenance of the right to use the NF Mark Condoms

Dear Sir,

I wish to apply, as ……(1), representing the company ……(2), to maintain the right to use the NF mark for products named below, in accordance with the NF062 certification regulations,

which differ from the products approved for the NF Mark only by the trademark and reference.

This application pertains to products sold through means of(3): .....

Reference of the basic model with NF certification		New trademark(s) and/or trade reference(s) requested
trademark and reference already accepted or in the process of being accepted	NF certificate no.	

The commitment from the above mentioned distributor is attached (see Appendix 2), as well as the following documents:
- Copy of the valid CE marking certificate for the references covered by the maintenance application;
- Draft marking of the individual packaging (foil);
- Draft marking of the sales packaging;
- Draft instructions (where applicable);
- Certificate concerning the national or international registration of the trade reference(s) covered by the maintenance application;

Stamp and signature of Holder
or of authorised representative (*):

Date

---

(1) Position
(2) Identification of the company (head office)
(3) Distributor's name and address
(*) Concerns a manufacturer outside the European economic area

APPENDIX 2 of part 4

ATTACHMENT WITH APPLICATION FOR MAINTENANCE OF THE RIGHT TO USE THE NF MARK

(Distributor's undertaking to be written on the distributor's letterhead paper)

I the undersigned,_____

acting as_____

of the company: _____

acknowledge that by affixing my trademark _____ in the place of / in addition to the trademark of the aforementioned certified models, I am bound to assuming the associated responsibilities.

In particular, I declare that I hold an exclusive right to use these trademarks and references, having registered them in compliance with industrial property legislation in force,

and I agree to market the aforementioned model(s) for which this application is made without making any change of any type whatsoever.

Done at on

Signature

Distributor's stamp:

Stamp and signature of producer
or authorised representative:

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AFNOR Certification
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75724 PARIS Cedex 15
Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37
www.lne.fr

CERTIFICATION RULES

NF MARK CONDOMS

PART 5

PARTICIPATING ORGANISATIONS

CONTENTS

Rev. 13 - May 2018

5.1. AFNOR CERTIFICATION

AFNOR is the owner of the NF mark and has granted an exclusive operating licence to AFNOR CERTIFICATION. AFNOR CERTIFICATION manages and oversees the NF certification system, which defines the rules of governance and the modalities of operation of the NF mark.

5.2. MANDATED BODY

AFNOR Certification entrusts management of the Mark application to the LNE.

Under this authorisation, the LNE is answerable to AFNOR Certification for all management operations entrusted to it, as set out in Article 3 of the General Rules of the NF Mark.

All persons involved in the NF mark process are bound to professional secrecy under Article 8 of the General Rules of the NF Mark. If necessary, on request from manufacturers, an agreement can be signed between the LNE and the manufacturer.

5.3. AUDIT BODY

The LNE entrusts audits to the following organisations:

LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS (LNE)
1, rue Gaston Boissier
75724 PARIS Cedex 15 - France
Tel. 01 40 43 37 00

However, it may call upon the expertise of duly qualified external auditors according to the LNE's procedures. This outsourcing of audits is formalised in the form of contracts (due to independence and confidentiality requirements)

The holder or applicant must facilitate the operations that agents in charge of audits are required to carry out in the context of their mission.

The LNE must be informed of any challenge concerning the members of an audit team within 10 days from when the audit team receives the notification in order for it to be taken into account.

5.4. TEST BODIES

The LNE entrusts the tests to the independent laboratories named below:

LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS (LNE)
Direction des essais – Pôle Essais en Environnement et Médical –
Département Médical
29, avenue Roger Hennequin
78197 TRAPPES-ELANCOURT
Tel. 01.30.69.10.00.

5.5. STEERING COMMITTEE

5.5.1. COMMITTEE MEMBERS

A steering committee is formed. All holders and experts, along with any other interested parties are invited to take part in the steering committee.

The steering committee is responsible for:
- issuing an opinion concerning the certification rules and their updates,
- issuing an opinion concerning projected brand-related communication or promotion actions. Promotional actions are covered by a specific budget that must be validated by the committee,
- issuing an opinion on the summary of all inspections performed. The steering committee must issue these opinions in accordance with the principles of impartiality.

The LNE convenes the committee members, or informs them in writing, at least once per year, to present an overview of all inspections performed.

Each committee member undertakes to:
- contribute, through his/her expertise, to the correct functioning of the NF Mark,
- maintain the confidentiality of all individual information it may receive, this until publication of this information by AFNOR Certification or the LNE,
- regularly attend meetings and, where applicable, to regularly inform his/her deputy and provide this latter with the documents,
- contribute to the growth of the NF Mark, i.e. promote products or services certified by the mark.

Members' mandate is renewable by tacit agreement.

In order to preserve the Commission's credibility and work efficiency, the LNE reserves the right to terminate a member's mandate in the following cases:
- failure to observe the confidentiality undertaking,
- repeated and unjustified failure to attend meetings,
- general lack of observance of the aforementioned commitments.

The LNE chairs the committee and fosters consensus.

Exercising the duties of Steering Committee member is strictly personal. In the event of absence, however, a deputy is designated and named under the same conditions as the incumbents.

The LNE drafts the committee meeting minutes, highlighting any observations and proposals made, along with any positions contrary to the opinion issued by the committee. These minutes are sent to all Steering Committee members.

The LNE calls upon AFNOR Certification as required to take part in committee meetings.

In the context of the revision of these certification rules, the LNE organizes the consultation and validation of the certification referential (as per the requirements of the NF X 50-067 standard with, in particular, consultation of AFNOR Certification as a stakeholder).

5.5.2. STEERING COMMITTEE COMPOSITION

The steering committee consists of a representation of the interested parties associated with the NF Mark – Condoms. The list of committee members, shown below, is provided for information purposes. It is non-exhaustive and may be changed as required. An up-to-date complete list of committee members is kept by the LNE.

Certification body
The representative(s) of the body mandated by LNE – Multi-sector Certification Cluster

Manufacturers, Distributors
All NF Mark holders

Users and prescribers
Representatives of:
- French national institute for consumer affairs
- Other

Bodies, laboratories and experts
- Test laboratory representative(s)
- AFNOR NORMALISATION representative

Authorities
Representatives of:
- French directorate-general for health.
- Other

5.6. LNE READING COMMITTEE

The reading committee is responsible for rendering an opinion on the certification decision and is composed of at least:
- one management representative (who can act as certification project manager having not participated in the audit),
- a certification project head independent of the file presented (who has not participated in the audit and is not in charge of the file),
- a certification project head in charge of presenting the file.

The committee is chaired by the LNE management representative.

The reading committee is responsible for:
- reviewing the audit and test reports and formulating an opinion and a recommendation on the decisions to be taken,
- where appropriate, considering in the first instance appeals against decisions of the LNE and formulating an opinion on the follow-up,
- evaluating the quality of reports.

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CERTIFICATION RULES

NF MARK CONDOMS

PART 6

APPLICABLE FEES – TERMS OF PAYMENT

CONTENTS

Rev. 13 – May 2018

The pricing schedule for the current year is available free of charge on the LNE website (www.lne.fr) or on request from the LNE.

6.1. APPLICABLE FEES

Fees for the services involved in obtaining certification and surveillance of certified products are indicated in a list of charges which may be revised annually. The list of charges for the current year is sent to all holders of the mark.

A special budget, decided each year in discussion with the committee, is set aside for promotional actions.

The fees are given in Euros, excluding tax. With regard to test fees, samples must be delivered to the Mark laboratory carriage-free and customs-cleared if necessary.

6.1.1. LIVING AND TRAVELLING EXPENSES ARE INVOICED AS FOLLOWS:

Living and travelling costs are payable by the applicant or holder.

Living and travelling expenses are invoiced as follows:

Travel in mainland France

- living expenses
  Food and accommodation expenses incurred by the LNE (except those directly paid by the manufacturer) are subject to an all-in charge per night spent on the spot.

- travelling expenses
Travelling expenses incurred by the LNE (except those directly paid by the manufacturer) are subject to an invoice based on their actual cost.

Travel abroad

Food and accommodation expenses incurred by the LNE (except those directly paid by the manufacturer) are subject to an all-in charge according to the scale applicable to the country concerned.

Travelling expenses incurred by the LNE (except those directly paid by the manufacturer) are subject to an invoice based on their actual cost.

6.1.2. CANCELLATION OF AN AUDIT

Cancellation of an audit whose date has been fixed by agreement between the LNE and the audited company is invoiced as follows:

- cancellation 15 days to 8 days before the scheduled date: 50 % of the audit fee
- cancellation 7 to 3 days before the scheduled date: 75 % of the audit fee
- cancellation 2 days before the scheduled date: 100 % of the audit fee.

Travelling expenses can be invoiced up to 100% if they are not reimbursable or subject to retention/penalties.

6.2. TERMS OF PAYMENT

6.2.1. COLLECTING PAYMENT

The LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS, the mandated body, 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 inspection and operating responsibilities incumbent on it by virtue of these regulations.

If the first enforcement order, sent by recorded delivery, does not result in payment of the total amount due within one month, the LNE will be entitled to take precautionary measures with regard to the certifications issued under the NF mark, for all the holder's accepted products.

6.2.2. OBTAINING CERTIFICATION

The services correspond to examination of the files, the audits and tests, for each application.

The fee for examination of the file is paid as a single sum when the application is filed and covers file examination, presenting the file to the Committee and the contribution to the general management of the mark.

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

6.2.3. CERTIFIED PRODUCT SURVEILLANCE

Invoicing covers the right to use the NF mark, passed on to AFNOR Certification, file monitoring, the audit and tests.

If acceptance is granted during the course of the year, the amounts invoiced correspond to the services provided, file monitoring (technical investigation of the case) is invoiced pro rata temporis.

After certification of a product, an annual right to use the NF Mark is invoiced to the holder and paid to AFNOR CERTIFICATION.

This licence fee is intended to cover:

- general operation of the NF mark (management of the NF mark's governing bodies, quality system, etc.)
- defence of the NF mark: filing and protecting the mark, legal advice, processing of unauthorised use of the NF mark, legal costs,
- contribution to the general promotion of the NF mark.

The amount relative to the file monitoring (technical examination of the file) remains due even if the certification is withdrawn or suspended following a decision by the LNE or at the holder’s request.

As long as it remains in the holder's stock of NF-marked products, inspections are maintained as is the billing of related costs, as file monitoring (technical investigation of the case) is invoiced pro rata temporis.

6.2.4. ADDITIONAL VERIFICATIONS

Costs resulting from additional verifications resulting from a decision by the LNE are payable by the applicant/holder, regardless of the results.