Section Laboratoires

ATTESTATION D'ACCREDITATION

ACCREDITATION CERTIFICATE

N° 1-1021 rév. 6

Le Comité Français d'Accréditation (Cofrac) atteste que :
The French Committee for Accreditation (Cofrac) certifies that:

ICARE
N° SIREN : 402946917

Satisfait aux exigences de la norme **NF EN ISO/CEI 17025 : 2005**
Fulfils the requirements of the standard

et aux règles d'application du Cofrac pour les activités d'analyses/essais/étalonnages en :
and Cofrac rules of application for the activities of testing/calibration in:

ENVIRONNEMENT / ENVIRONNEMENT CONTROLE (AIR, EAU et SURFACES) - QUALITE DE L'EAU - BIOCONTAMINATION
ENVIRONMENT / CONTROLLED ENVIRONMENT (AIR, WATER and SURFACES) - WATER QUALITY - BIOCONTAMINATION
PRODUITS CHIMIQUES ET BIOLOGIQUES, EQUIPEMENTS MEDICAUX / DISPOSITIFS MEDICAUX - PRODUITS BIO-ACTIFS (MEDICAMENTS, COSMETIQUES, ANTISEPTIQUES ET DESINFECTANTS)
CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL DEVICES / MEDICAL DEVICES - BIOCIDES AND HYGIENE PRODUCTS (MEDICALS, COSMETICS, ANTISEPTICS AND DISINFECTANTS)

réalisées par / *performed by* :

ICARE
Biopôle Clermont-Limagne
BP 60006
63360 SAINT BEAUZIRE

et précisément décrites dans l'annexe technique jointe
and precisely described in the attached technical appendix

L'accréditation suivant la norme internationale homologuée NF EN ISO/IEC 17025 est la preuve de la compétence technique du laboratoire dans un domaine d'activités clairement défini et du bon fonctionnement dans ce laboratoire d'un système de management adapté (cf. communiqué conjoint ISO-ILAC-IAF en vigueur disponible sur le site internet du Cofrac www.cofrac.fr)

Accreditation in accordance with the recognised international standard NF EN ISO/IEC 17025 demonstrates the technical competence of the laboratory for a defined scope and the proper operation in this laboratory of an appropriate management system (see current Joint ISO-ILAC-IAF Communiqué available on Cofrac web site www.cofrac.fr) .

Le Cofrac est signataire de l'accord multilatéral d'EA pour l'accréditation, pour les activités objets de la présente attestation.
Cofrac is signatory of the European co-operation for Accreditation (EA) Multilateral Agreement for accreditation for the activities covered by this certificate.

Date de prise d'effet / *granting date :* **01/08/2019**
Date de fin de validité / *expiry date :* **31/07/2024**

Pour le Directeur Général et par délégation
On behalf of the General Director

La Responsable du Pôle Biologie-Agroalimentaire,
Pole manager - Biology-Agri-food,

Safaa KOBBI ABIL

La présente attestation n'est valide qu'accompagnée de l'annexe technique.
This certificate is only valid if associated with the technical appendix.

L'accréditation peut être suspendue, modifiée ou retirée à tout moment. Pour une utilisation appropriée, la portée de l'accréditation et sa validité doivent être vérifiées sur le site internet du Cofrac (www.cofrac.fr).
The accreditation can be suspended, modified or withdrawn at any time. For a proper use, the scope of accreditation and its validity should be checked on the Cofrac website (www.cofrac.fr).

Cette attestation annule et remplace l'attestation N° 1-1021 Rév 5.
This certificate cancels and replaces the certificate N° 1-1021 Rév 5.

Seul le texte en français peut engager la responsabilité du Cofrac.
The Cofrac's liability applies only to the french text.

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TECHNICAL ANNEX

to accreditation N° 1-1021 rev. 6

The accreditation relates to the services provided by:

ICARE
Biopôle Clermont-Limagne
BP 60006
F-63360 SAINT BEAUZIRE

In the following unit:

- ICARE

It concerns:

TECHNICAL UNIT: ICARE

FIXED SCOPE

# ENVIRONMENT / CONTROLLED ENVIRONMENT (WATER) / Sampling – Collection *(Environmental testing– HP ENV)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Water *(including waters described as per the pharmacopoeia, purified waters, sterile water for injection, highly-purified waters)*	Sampling of water for microbiological and endotoxin analyses	Instantaneous sampling (single run)	NF EN ISO 14698-1 In-house method IC-EXT-PLV-EA

Fixed scope: *The laboratory is recognized as competent to perform the sampling, in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating mode are not permitted.*

FIXED SCOPE

ENVIRONMENT / BIOCONTAMINATION / Sampling– Collection *(Tests for assessing aerobiocontamination)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Controlled environment: -Health facility (clean room, operating room) -Production environment, laboratory	Viable aerobic flora	Sampling by impaction on solid surface (agar medium)	NF EN ISO 14698-1 In-house method INT025
	Yeasts - Moulds	Sampling by impaction on solid surface (agar medium)	NF EN ISO 14698-1 In-house method INT025

Fixed scope: *The laboratory is recognized as competent to perform the sampling, in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating mode are not permitted.*

FIXED SCOPE

ENVIRONMENT / BIOCONTAMINATION / Sampling– Collection *(Tests for assessing surface biocontamination)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Controlled environment: -Health facility (clean room, operating room) -Production environment, laboratory Type of surface (work surface, staff, textiles, floor, equipment)	Viable aerobic flora	Sampling by applying a "count tact" type box	NF EN ISO 14698-1 In-house method INT022
	Yeasts - Moulds	Sampling by applying a "count tact" type box	NF EN ISO 14698-1 In-house method INT022

Fixed scope: *The laboratory is recognized as competent to perform the sampling, in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating mode are not permitted.*

FIXED SCOPE

ENVIRONMENT / BIOCONTAMINATION / Microbiological analyses *(Tests for assessing surface biocontamination)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Controlled environment: -Health facility (clean room, operating room) -Production environment, laboratory Type of surface (work surface, staff, textiles, floor, equipment)	Viable aerobic flora	Sample count using a “Count tact” type box	NF EN ISO 14698-1 In-house method INT022
	Yeasts - Moulds	Sample count using a “Count tact” type box	NF EN ISO 14698-1 In-house method INT022

Fixed scope: *The laboratory is recognized as competent to perform the tests, in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating mode are not permitted.*

FIXED SCOPE

ENVIRONMENT / BIOCONTAMINATION / Microbiological analyses *(Tests for assessing aerobiocontamination)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Controlled environment: -Health facility (clean room, operating room) -Production environment, laboratory	Viable aerobic flora	Count taken from a sample by impaction on solid surface (agar medium)	NF EN ISO 14698-1 Internal method INT025
	Yeasts - Moulds	Count taken from a sample by impaction on solid surface (agar medium)	NF EN ISO 14698-1 Internal method INT025

Fixed scope: *The laboratory is recognized as competent to perform the tests, in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating mode are not permitted.*

FLEX 1 SCOPE

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIO-ACTIVE PRODUCTS / Microbiological analyses *(Microbiology applied to fine chemistry, cosmetic, health and safety products: biological methods and medical devices – LAB GTA 19/131- 3 and 160)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Medical devices Miscellaneous pharmaceutical or other products	Bacterial endotoxin tests: Determination of the concentration of bacterial endotoxins using the Limulus amoebocyte lysate (LAL) test	Photometric method (kinetic colorimetry) with interference identification	Pharmacopoeia 2.6.14 or USP<85> and <161> Method D

Flexible scope FLEX1: *The laboratory is recognized as competent to perform the tests, in compliance with the referenced methods and their subsequent revisions.*

FLEX 1 SCOPE

# **ENVIRONMENT / WATER QUALITY / Microbiological analyses** *(Microbiological analyses of water – LAB GTA 23)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Pharmacopoeia waters (including highly-purified water, sterile water for injection, purified water).	Viable total aerobic germs, yeasts and moulds	Count by membrane filtration Incubation	Pharmacopoeia PE 2.6.12 or USP<61> Monographs
Waters described as per the Pharmacopoeia	Bacterial endotoxins	Determination of the concentration of bacterial endotoxins using the Limulus amoebocyte lysate (LAL) test Photometric methods with interference identification (kinetic colorimetry)	Pharmacopoeia Monographs n°*1167* PE 2.6.14 or USP <85> and <161> Method D

Flexible scope FLEX1: *The laboratory is recognized as competent to perform the tests, in compliance with the referenced methods and their subsequent revisions.*

FLEX 1 SCOPE

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Microbiological analyses *(Microbiology applied to fine chemistry, cosmetic, health and safety products medical devices – LAB GTA 19/160)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Medical devices	Control germ contamination: Method for estimation of microorganisms population	Immersion or elution, enumeration a- Filtration b- Inclusion c- MPN and others	NF EN ISO 11737-1
Sterile medical devices	Sterility tests carried out while validating a sterilisation process: Detection of micro-organisms	Direct inoculation Filtration over membrane	NF EN ISO 11737-2
Sterile medical devices Sterile pharmaceutical products	Sterility tests outside the scope of validation of a sterilisation process: aerobic and anaerobic bacteria, yeasts, moulds (product expiry date must be checked in particular)	Direct inoculation Filtration over membrane	Pharmacopoeia 2.6.1 USP <71>
Sterile medical devices Sterile pharmaceutical products	Tests on biological sterilisation indicators	Determination of number of micro-organisms Detection of growth inhibition Determination of value D Survival-destruction response characteristic	NF EN ISO 11138-1 NF EN ISO 11138-2 NF EN ISO 11138-3

Flexible scope FLEX1: *The laboratory is recognized as competent to perform the tests, in compliance with the referenced methods and their subsequent revisions.*

FLEX 1 SCOPE

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physicochemical analyses *(Tests to determine the toxicity of materials and medical devices)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**PRINCIPLE OF THE METHOD**	**METHOD REFERENCE**
Medical devices sterilised with ethylene oxide (in contact with patient)	Residues from sterilisation with ethylene oxide (ethylene oxide, ethylene hydrochloride and ethylene glycol)	Simulated-use extraction method: Quantification by GPC	NF EN ISO 10993-7
Medical devices sterilised with ethylene oxide (in contact with patient)	Residues from sterilisation with ethylene oxide (ethylene oxide, ethylene hydrochloride and ethylene glycol)	Exhaustive thermal extraction method: Quantification by GPC	NF EN ISO 10993-7

Flexible scope FLEX1: *The laboratory is recognized as competent to perform the tests, in compliance with the referenced methods and their subsequent revisions.*

[#] *Accreditation made mandatory under French law, as detailed in the text cited in reference in document Cofrac LAB INF 99 and available from www.cofrac.fr.*

Effective date: **01/08/2019** Validity end date: **31/07/2024**

La Responsable d'accréditation
The Accreditation Manager

Cassandre CHOPLIN

This technical annex cancels and replaces technical annex 1-1021 Rev. 5.

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