cofrac

Convention N° 633

Section Laboratoires

ATTESTATION D'ACCREDITATION

ACCREDITATION CERTIFICATE

N° 1-1021 rév. 14

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

LABORATOIRE ICARE
N° SIREN : 402946917

Satisfait aux exigences de la norme **NF EN ISO/IEC 17025 : 2017**
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
EQUIPEMENTS INDUSTRIELS ET PRODUITS D'INGENIERIE / SALLES PROPRES ET A ENVIRONNEMENT MAITRISE
INDUSTRIAL EQUIPMENTS AND ENGINEERING PRODUCTS / CLEAN ROOMS AND ASSOCIATED CONTROLED ENVIRONMENT
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:*

LABORATOIRE ICARE
Biopôle Clermont-Limagne
Rue Emile Duclaux
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:* **01/08/2024**
Date de fin de validité / *expiry date:* **31/07/2029**

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 13.
This certificate cancels and replaces the certificate N° 1-1021 Rév 13.

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

Comité Français d'Accréditation - 52, rue Jacques Hillairet 75012 PARIS
Tél. : +33 (0)1 44 68 82 20 – Fax : 33 (0)1 44 68 82 21 Siret : 397 879 487 00031 www.cofrac.fr

TECHNICAL ANNEX

to accreditation N° 1-1021 rev. 14

Accreditation relates to the services performed by:

LABORATOIRE ICARE
Biopôle Clermont-Limagne
Rue Emile Duclaux
63360 SAINT BEAUZIRE

In its units:

- ICARE
- PHYSICO-CHEMISTRY/PACKAGING
- MICROBIAL STRAINS

It covers:

TECHNICAL UNIT: ICARE

FIXED SCOPE

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

***Fixed scope**: The laboratory is recognized to be competent to perform the methods described in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating procedure are not permitted.*

FIXED AND FLEXIBLE (FLEX1) SCOPE

ENVIRONMENT/BIOCONTAMINATION / Sampling – Collection Tests for assessing aerobiocontamination – Sampling strategy			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Controlled environment: - Health facility (clean room, operating room) - Production environment, laboratory	Establishment of the sampling strategy for assessing aerobiocontamination	Selection of sampling and analysis methods to be used Determination of the number of samples Choice of measurement locations and periods	Internal method INT025 NF EN 17141* ISO 14698-1*
	Establishment of diagnosis in CFU/m³ of air	Determination of microorganism concentrations	

***Fixed scope**: The laboratory is recognized to be competent to perform the methods described in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating procedure are not permitted.*
** **Flexible scope (FLEX1)**: The laboratory is recognized as competent to perform the referenced methods and their subsequent revisions.*

FIXED AND FLEXIBLE (FLEX1) SCOPE

ENVIRONMENT/BIOCONTAMINATION/Sampling – Collection *(Tests for assessing aerobiocontamination)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Controlled environment: - Health facility (clean room, operating room) - Production environment, laboratory	Viable aerobic flora Yeasts - Molds	Direct-impact sampling (agar culture medium)	Internal method INT025 NF EN 17141* ISO 14698-1*

***Fixed scope**: The laboratory is recognized to be competent to perform the methods described in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating procedure are not permitted.*
** **Flexible scope (FLEX1)**: The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FIXED AND FLEXIBLE (FLEX1) SCOPE

ENVIRONMENT/BIOCONTAMINATION/Sampling – collection (Tests for assessing surface biocontamination – Sampling strategy)			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Controlled environment: - Health facility (clean room, operating room) - Production environment, laboratory Type of surface (work surfaces, personnel, textiles, floor, equipment)	Establishment of the sampling strategy for assessing surface biocontamination	Definition of the measurement target Selection of sampling and analysis methods to be used Determination of the number of samples Choice of locations	Internal method INT022 NF EN 17141* ISO 14698-1*
	Establishment of diagnosis in CFU/ surface sampled	Determination of microorganism concentrations	

***Fixed scope**: The laboratory is recognized to be competent to perform the methods described in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating procedure are not permitted.*
** **Flexible scope (FLEX1)**: The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FIXED AND FLEX1 SCOPE

ENVIRONMENT / BIOCONTAMINATION / Sampling– Collection *(Tests for assessing surface biocontamination)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Controlled environment: - Health facility (clean room, operating room) - Production environment, laboratory Type of surface (work surfaces, personnel, textiles, floor, equipment)	Viable aerobic flora Yeasts - Molds	Collection by contact plate application	Internal method INT022 NF EN 17141* ISO 14698-1*

***Fixed scope**: The laboratory is recognized to be competent to perform the methods described in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating procedure are not permitted.*
** **Flexible scope (FLEX1)**: The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FIXED AND FLEXIBLE (FLEX1) SCOPE

ENVIRONMENT/BIOCONTAMINATION/Microbiological analyses *(Tests for assessing surface biocontamination)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Controlled environment: - Health facility (clean room, operating room) - Production environment, laboratory	Viable aerobic flora Yeasts - Molds	Enumeration from direct-impact sampling (agar culture medium)	Internal method INT025 NF EN 17141* ISO 14698-1*

***Fixed scope**: The laboratory is recognized to be competent to perform the methods described in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating procedure are not permitted.*
** **Flexible scope (FLEX1)**: The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FIXED AND FLEXIBLE (FLEX1) SCOPE

ENVIRONMENT/BIOCONTAMINATION/Microbiological analyses *(Tests for assessing surface biocontamination)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Controlled environment: - Health facility (clean room, operating room) - Production environment, laboratory Type of surface (work surfaces, personnel, textiles, floor, equipment)	Viable aerobic flora Yeasts - Molds	Enumeration from collection by contact plate application	Internal method INT025 NF EN 17141* ISO 14698-1*

***Fixed scope**: The laboratory is recognized to be competent to perform the methods described in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating procedure are not permitted.*
** **Flexible scope (FLEX1)**: The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FLEXIBLE (FLEX1) SCOPE

# ENVIRONMENT/WATER QUALITY/ Microbiological analyses *(Microbiological analyses of water – LAB GTA 23)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Water from health facilities and pharmaceutical and cosmetic grade water	Enumeration of total viable aerobic germs, from yeasts and molds	Enumeration using membrane filtration Incubation	Applicable pharmacopoeia: 2.6.12 or USP <61> Monographs
Water from health facilities and pharmaceutical and cosmetic grade water	Bacterial endotoxins	Determination of bacterial endotoxin concentration using the limulus amoebocyte lysate (LAL) test: Photometric methods with check for interference : Kinetic colorimetry	Applicable pharmacopoeia: Monographs n°1167 2.6.14 or USP <85> and <161> Method D

***Flexible scope (FLEX1)**: The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FLEXIBLE (FLEX 1) SCOPE

CHEMICAL AND BIOLOGICAL PRODUCTS /BIOCIDES AND HYGIENE PRODUCTS/MICROBIOLOGICAL TESTS *(Microbiological tests applied to pharmaceuticals and cosmetics - LAB GTA 19)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Diverse 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	Current pharmacopoeia EP 2.6.14 USP <85> and <161> Method D
Sterile pharmaceuticals products	Sterility test: - search for aerobic and anaerobic bacteria - search for yeasts and molds	Search using: - direct inoculation - membrane filtration	Current pharmacopoeia EP 2.6.1 or USP < 71> Monographs
Sterile pharmaceuticals products	Tests on biological indicators for ethylene oxide sterilization	Determination of the number of viable micro-organisms Determination of growth inhibition Determination of value D Survival-destruction response characteristic	NF EN ISO 11138-1 NF EN ISO 11138-2
Sterile pharmaceuticals products	Tests on biological indicators for damp heat sterilization	Determination of the number of viable micro-organisms Determination of growth inhibition Determination of value D Survival-destruction response characteristic	NF EN ISO 11138-1 NF EN ISO 11138-3
Sterile pharmaceuticals products	Tests on biological indicators for dry heat sterilization	Determination of the number of viable micro-organisms Determination of growth inhibition Determination of value D Survival-destruction response characteristic	NF EN ISO 11138-1 NF EN ISO 11138-3

Flexible scope (FLEX1): *The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FLEXIBLE (FLEX 1) SCOPE

CHEMICAL AND BIOLOGICAL PRODUCTS/MEDICAL DEVICES/ MICROBIOLOGICAL TESTS *(Microbiological tests applied to medical devices - LAB GTA 19)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices	Bacterial endotoxin tests Determination of the concentration of bacterial endotoxins using the Limulus amoebocyte lysate (LAL) test	Photometric methods with detection of interference: kinetic colorimetry	Current pharmacopoeia EP 2.6.14 or USP <85> and <161> Method D
Medical devices	Microbial contamination check: - Validation of the method for estimating the population of micro-organisms - Tests: application of the validated method	Immersion or elution then enumeration using: - filtration - inclusion - 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 Search using membrane filtration	NF EN ISO 11737-2

CHEMICAL AND BIOLOGICAL PRODUCTS/MEDICAL DEVICES/ MICROBIOLOGICAL TESTS *(Microbiological tests applied to medical devices - LAB GTA 19)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices	Bacterial endotoxin tests: Determination of the concentration of bacterial endotoxins using the Limulus amoebocyte lysate (LAL) test	Photometric methods with detection of interference: kinetic colorimetry, endpoint colorimetry	NF ISO 11737-3
Sterile medical devices	Sterility tests outside the context of sterilisation process validation: Search for aerobic and anaerobic bacteria, yeasts and molds (check in particular the expiry date of a product)	Direct inoculation Search by membrane filtration	Current pharmacopoeia EP 2.6.1 or USP < 71> With validation of the SIP (Sample Item portion)
Medical devices	Tests on biological indicators for ethylene oxide sterilization	Determination of the number of viable micro-organisms Determination of growth inhibition Determination of value D Survival-destruction response characteristic	NF EN ISO 11138-1 NF EN ISO 11138-2
Medical devices	Tests on biological indicators for damp heat sterilization	Determination of the number of viable micro-organisms Determination of growth inhibition Determination of value D Survival-destruction response characteristic	NF EN ISO 11138-1 NF EN ISO 11138-3
Medical devices	Tests on biological indicators for dry heat sterilization	Determination of the number of viable micro-organisms Determination of growth inhibition Determination of value D Survival-destruction response characteristic	NF EN ISO 11138-1 NF EN ISO 11138-3

***Flexible scope (FLEX1)**: The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FLEXIBLE (FLEX 1) SCOPE

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT/MEDICAL DEVICES **Physico-chemical tests** *(Tests for determining the toxicity of medical materials and devices)*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices sterilized with ethylene oxide (in contact with the patient)	Ethylene oxide sterilization residues (ethylene oxide, ethylene hydrochloride and ethylene glycol)	Simulated use extraction method: Determination by GPC	NF EN ISO 10993-7
Medical devices sterilized with ethylene oxide (in contact with the patient)	Ethylene oxide sterilization residues (ethylene oxide, ethylene hydrochloride and ethylene glycol)	Exhaustive thermal extraction method: Determination by GPC	NF EN ISO 10993-7

***Flexible scope (FLEX1)**: The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FLEXIBLE (FLEX 1) SCOPE

INDUSTRIAL EQUIPMENT AND ENGINEERING PRODUCTS/Clean rooms and associated controlled environment / Physical tests, Performance or proficiency tests					
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**MEASUREMENT RANGE**	**METHOD PRINCIPLE**	**METHOD REFERENCE**	**TEST LOCATION**
BSC type 2 biological safety cabinet	Number of particles as a function of diameter	≥ ISO 5 ≥ Class A	Measurement using an optical particle counter	NF EN ISO 14644-1 NF EN ISO 14644-3 Good Manufacturing Practices (GMP 2022)	On site Temperature from 0°C to 40°C. Humidity from 5% to 90%
	Downspeed	0.15 m/s to 30 m/s	Measurement with a hot wire anemometer	NF EN 12469 Good Manufacturing Practices (GMP 2022)	
	Volume flow rate	50 m^3/h to 10000 m^3/h	Calculation following velocity measurements with a hot wire or propeller type anemometer	NF EN 12469	
	Differential pressure	0 Pa to 500 Pa	Measurement with pressure gauge		
	Filter integrity	0.01% to 100%	Generation of an aerosol and measurement of penetration downstream of the filter with a photometer	NF EN 12469 NF EN ISO 14644-3	

FLEX1 flexible scope *The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FLEXIBLE (FLEX 1) SCOPE

INDUSTRIAL EQUIPMENT AND ENGINEERING PRODUCTS/Clean rooms and associated controlled environment / Physical tests, Performance or proficiency tests					
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**MEASUREMENT RANGE**	**METHOD PRINCIPLE**	**METHOD REFERENCE**	**TEST LOCATION**
Clean rooms and associated controlled environments	Number of particles as a function of diameter	≥ ISO 5 ≥ Class A	Measurement using an optical particle counter	NF EN ISO 14644-1 NF EN ISO 14644-3 Good Manufacturing Practices (GMP 2022)	On site Temperature from 0°C to 40°C. Humidity from 5% to 90%
	Recovery time	≤ 30 min	Counting particles at regular time intervals after contamination with an aerosol	NF EN ISO 14644-3	
	Air velocity	0.15 m/s to 30 m/s	Measurement with a hot wire anemometer	NF EN ISO 14644-3 Good Manufacturing Practices (GMP 2022)	
		0.30 m/s to 30 m/s	Measurement with a propeller anemometer		
	Differential pressure	-500 Pa to 500 Pa	Measurement with pressure gauge	NF EN ISO 14644-3	
	Temperature	0°C to 40°C	Measurement with a thermometer		
	Relative humidity	5% to 90% (for T between 0°C and 40°C)	Measurement with a hygrometer		
	Air flow	50 m^3/h to 3500 m^3/h	Measurement with a balometer		
		50 m^3/h to 10000 m^3/h	Calculation following velocity measurements with a hot wire type anemometer		
		100 m^3/h to 10000 m^3/h	Calculation following velocity measurements with a propeller type anemometer		
	Filter integrity	From 001% to 100%	Generation of an aerosol and measurement of penetration downstream of the filter with a photometer		

FLEX1 flexible scope *The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

TECHNICAL UNIT 2: PHYSICO-CHEMISTRY/PACKAGING

FIXED AND FLEXIBLE (FLEX1) SCOPE

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT/MEDICAL DEVICES/ Physico-chemical tests			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices	Total Organic Carbon (TOC)	**Preparation:** Solid/liquid extraction **Determination:** TOC meter	NF ISO 19227 Extraction: Internal method* INT147 Determination: Current pharmacopoeia EP 02/02/2044
Medical devices	Total hydrocarbons (THC)	**Preparation:** Solid/liquid extraction **Determination:** Gas phase chromatography	NF ISO 19227 Extraction: Internal method * INT102 Determination: NF EN ISO 9377-2

**Fixed scope: The laboratory is recognized to be competent to perform the methods described in strict compliance with the methods mentioned in the scope of accreditation. Technical changes to the operating procedure are not permitted.*

***Flexible scope (FLEX1):** The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

FLEXIBLE (FLEX 1) SCOPE

ENVIRONMENT/WATER QUALITY/Physical-chemical tests			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Purified water, Water for injection, Process water, pure steam	Total Organic Carbon (TOC)	**Determination:** TOC meter	Current pharmacopoeia EP 2.2.44 and USP <643> European Pharmacopoeia M0008 Purified water M0169, Water for injection

***Flexible scope (FLEX1):** The laboratory is recognized to be competent to perform the referenced methods and their subsequent revisions.*

TECHNICAL UNIT 3: MICROBIAL STRAINS

FLEXIBLE (FLEX 1) SCOPE

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT/MEDICAL DEVICES/ Microbiological tests (20-8 microbiological portion)			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Mask for medical use	Determination of bacterial filtration efficiency (BFE)	Preparation of a calibrated *Staphylococcus aureus* inoculum Vacuum aspiration of a bacterial aerosol through the mask material and a six-stage impactor Incubation at 37°C Colony enumeration Calculation of the efficiency of bacterial filtration	NF EN 14683 (ANNEX B)

***Flexible scope (FLEX1):** The laboratory is recognized to be competent to perform 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.*

Granting date: **01/08/2024** Expiry date: **31/07/2029**

This technical annex cancels and replaces technical annex 1-1021 Rev. 13.