Section Laboratoires

ATTESTATION D'ACCREDITATION

ACCREDITATION CERTIFICATE

N° 1-1793 rév. 23

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

FILAB
N° SIREN : 491631891

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 :

MATERIAUX / MATERIAUX METALLIQUES
MATERIALS / METALLIC MATERIALS
PRODUITS CHIMIQUES ET BIOLOGIQUES, EQUIPEMENTS MEDICAUX / DISPOSITIFS MEDICAUX - PRODUITS BIO-ACTIFS (MEDICAMENTS, COSMETIQUES, ANTISEPTIQUES ET DESINFECTANTS) - PRODUITS COSMETIQUES ET PRODUITS D'HYGIENE
CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL DEVICES / MEDICAL DEVICES - BIOCIDES AND HYGIENE PRODUCTS (MEDICALS, COSMETICS, ANTISEPTICS AND DISINFECTANTS) - COSMETIC AND HYGIEN PRODUCTS

réalisées par / *performed by* :

FILAB
Ecoparc Dijon Bourgogne
80 rue Jean Louis Auguste Petitjean
21850 SAINT APOLLINAIRE

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 :* **04/11/2024**
Date de fin de validité / *expiry date :* **31/10/2025**

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

Le Responsable du Pôle Chimie Environnement,
Pole manager - Chemistry Environment,

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° 1-1793 Rév 22.
This certificate cancels and replaces the certificate N° 1-1793 Rév 22.

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
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Laboratories Section

TECHNICAL ANNEX

to accreditation N° 1-1793 rev. 23

Accreditation relates to the services performed by:

FILAB
Ecoparc Dijon Bourgogne
80 rue Jean Louis Auguste Petitjean
21850 SAINT APOLLINAIRE, FRANCE

In its units:

- **METALLURGY DIVISION**
- **CHEMISTRY/HEALTH DIVISION**

This concerns: see following pages

Technical unit: **METALLURGY DIVISION**

The accreditation relates to:

MATERIALS / METALLIC MATERIALS/ Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Unalloyed steels	Elements: C Mn Si S P Al	Optical emission spectrometry using a spark source on solid material after surface preparation	Internal method: FIL-DIJ-MOP-META-00001
	Elements: Mn Si P Al Ni Cr Mo V Cu Co Ti Nb B	Inductively coupled plasma-optical emission spectrometry (ICP-OES) after sample dissolution	Internal method: FIL-DIJ-MOP-META-10001
	Elements: C S	Combustion and infrared absorption on solid sample	Internal method: FIL-DIJ-MOP-META-00014
	Element: N	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META-01001
	Element: H	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META 09002
Low-alloy steels	Elements: C Mn Si S P Ni Cr Mo V Cu Al Co Ti Nb B	Optical emission spectrometry using a spark source on solid material after surface preparation	Internal method: FIL-DIJ-MOP-META-00001
	Elements: Mn Si P Ni Cr Mo V Cu Al Co Ti Nb B	Inductively coupled plasma-optical emission spectrometry (ICP-OES) after sample dissolution	Internal method: FIL-DIJ-MOP-META-10001
	Elements: C S	Combustion and infrared absorption on solid sample	Internal method: FIL-DIJ-MOP-META-00014
	Element: N	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META-01001
	Element: H	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META 09002

MATERIALS / METALLIC MATERIALS/ Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
High-alloy steels	Elements: C Mn Si S P Ni Cr Mo V Cu Al Co Ti Nb B	Optical emission spectrometry using a spark source on solid material after surface preparation	Internal method: FIL-DIJ-MOP-META-00001
	Elements: Mn Si P Ni Cr Mo V Cu Al Co Ti Nb B	Inductively coupled plasma-optical emission spectrometry (ICP-OES) after sample dissolution	Internal method: FIL-DIJ-MOP-META-10001
	Elements: C S	Combustion and infrared absorption on solid sample	Internal method: FIL-DIJ-MOP-META-00014
	Element: N	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META-01001
	Element: H	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META-09002
Aluminium alloys	Elements: Mg Mn Si Zn Ni Cr Cu Fe Ti	Optical emission spectrometry using a spark source on solid material after surface preparation	Internal method: FIL-DIJ-MOP-META-00001
	Elements: Mg Mn Si Zn Ni Cr Cu Fe Ti Pb Zr	Inductively coupled plasma-optical emission spectrometry (ICP-OES) after sample dissolution	Internal method: FIL-DIJ-MOP-META-10002
Nickel alloys	Elements: C S	Combustion and infrared absorption on solid sample	Internal method: FIL-DIJ-MOP-META-00014
	Elements: Cr Co Al Fe Mn Ti Mo Zr B Si Cu P V Nb	Inductively coupled plasma-optical emission spectrometry (ICP-OES) after sample dissolution	Internal method: FIL-DIJ-MOP-META-21002
	Elements: N O	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META-01001
Titanium alloys	Elements: H	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META 09002
	Elements: N O	Reductive fusion and thermal conductivity on solid sample	Internal method: FIL-DIJ-MOP-META 01001
	Elements: Al Fe V Cu Cr Ni Si Mo Zr	Inductively coupled plasma-optical emission spectrometry (ICP-OES) after sample dissolution	Internal method: FIL-DIJ-MOP-META 00016

FIXED scope: The laboratory is recognised as competent to carry out the tests, in strict compliance with the methods referred to in the scope of accreditation. Technical modifications of the method are not authorized.

MATERIALS / METALLIC MATERIALS/ Metallographic tests (29-4)				
Subject	**Type of test or analysis**	**Characteristic measured or sought**	**Method reference**	**Comments/ Restrictions**
Metallic materials	Determination of grain size	Grain size index	ASTM E112 NF EN ISO 643	/

FLEX1 flexible scope: The laboratory is recognised as competent to carry out the sampling, in compliance with the referenced methods and their subsequent revisions.

MATERIALS / METALLIC MATERIALS/ Physical testing			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Metallic powders	Specific surface-area analysis	Freeze-drying and/or degassing Measurement by sorptometry (BET method)	PE 2.9.26 ISO 9277
Metallic powders	Particle size analysis	Suspended in a solution (if necessary) Liquid or dry laser particle-size analyser	ISO 13320 PE 2.9.31
Metallic powders	Bulk density	Helium pycnometry analysis	ASTM B923

FLEX1 flexible scope: The laboratory is recognised as competent to carry out the sampling, in compliance with the referenced methods and their subsequent revisions.

Technical unit: **CHEMISTRY/HEALTH DIVISION**

The accreditation relates to:

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS / Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Biocides and hygiene products	Determination of the content in trace metal elements and minerals	**Preparation:** Thermal decomposition, gold amalgam Open system wet digestion Solubility in aqueous medium Dilution **Detection and quantification:** AAS ICP-AES ICP-MS

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS / Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Dissolved active ingredient: solution for injection in vial (Lasix)	Determination of Chromium content	**Preparation:** Dilution **Detection and quantification:** ICP-AES ICP-MS	Internal method: FIL DIJ MOP IND 15003- *PE2.4.20/USP233*
Dissolved raw materials or in a powder form, for the manufacturing of a pharmaceutical or cosmetic product: Fat (behenic acid, vegetable glycerine)	Determination of Nickel content	**Preparation:** Open system wet digestion **Detection and quantification:** ICP-AES ICP-MS	Internal method: FIL DIJ MOP IND 15004- *PE2.4.20/USP233*
Dissolved raw materials or in a powder form, for the manufacturing of a pharmaceutical or cosmetic product: Fat (labrafac lopophile)	Determination of Lead content	**Preparation:** Open system wet digestion **Detection and quantification:** ICP-MS	Internal method: FIL DIJ MOP IND 15004- *PE2.4.20/USP233*
Excipient in the form of granules: PLA/PLGA/PCL co-polymer: (polylactic acid, lactic-co-glycolic acid,	Determination of Tin content	**Preparation:** Open system wet digestion **Detection and quantification:**	Internal method: FIL DIJ MOP IND 20001- *PE2.4.20/USP233*

polycaprolactone)		ICP-MS	
Dissolved raw materials or in a powder form, for the manufacturing of a pharmaceutical or cosmetic product: Collagen	Determination of Cadmium, Lead, Arsenic, Mercury, Cobalt, Vanadium, Nickel, Lithium, Antimony, Copper, Chromium, Molybdenum, Tin and Barium content	**Preparation:** Open system wet digestion **Detection and quantification:** ICP-MS	Internal method: FIL DIJ MOP IND 20002 - *PE2.4.20/USP233*

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / COSMETIC AND HYGIENE PRODUCTS / Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Cosmetic and hygiene products	Determination of the content in trace metal elements and minerals	**Preparation:** Open system wet digestion Thermal decomposition, gold amalgam **Detection and quantification:** AAS ICP-AES ICP-MS

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / COSMETIC AND HYGIENE PRODUCTS / Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Products in a powder form: **Eye shadow**	Determination of Cadmium content	**Preparation:** Open system wet digestion **Detection and quantification:** ICP-AES ICP-MS	Internal method: FIL DIJ MOP IND 15005-*PE2.4.20/USP233*
	Determination of Mercury content	**Preparation:** Thermal decomposition, gold amalgam **Detection and quantification:** AAS	Internal method: FIL DIJ MOP IND 15005-*PE2.4.20/USP233*

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS / Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Cosmetic products	Determination of organic contaminants at a target value	**Preparation:** Solid/liquid extraction **Assay:** GC-MS LC-UV

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS / Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Cosmetic products: Skin care cosmetics (e.g. lotion)	Determination of phthalates at the target value of 1 mg/kg: - Diisobutyl phthalate (DIBP) - Di-n-butyl phthalate (DnBP) - Dibutyl phthalate (DBP)	**Preparation:** Solid/liquid extraction **Assay:** GC-MS	Internal method: FIL-DIJ-MOP-EXP-21003
Cosmetic products: Skin care cosmetics (e.g. lotion, cream); Foaming products (e.g. shampoo); Hair dyes in powder form	Determination of 1,4-Dioxane at the target value of 10 mg/kg	**Preparation:** Solid/liquid extraction **Assay:** GC-MS	Internal method: FIL-DIJ-MOP-EXP-21002
Cosmetic products: Skin care cosmetics (e.g. lotion)	Determination of Bisphenol A (BPA) at the target value of 10 mg/kg	**Preparation:** Solid/liquid extraction **Assay:** LC-UV	Internal method: FIL-DIJ-MOP-EXP-21004
Cosmetic products: Skin care cosmetics (e.g. lotion, cream); Foaming products (e.g. shampoo)	Determination of aldehydes: Formaldehydes at the target value of 1 mg/kg	**Preparation:** Solid/liquid extraction **Assay:** LC-UV	Internal method: FIL-DIJ-MOP-EXP-22006

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Medical devices	Total hydrocarbon content (THC)	**Preparation:** Solid/liquid extraction **Detection and quantification:** Gas chromatography

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical Devices *(metallic)*	Total hydrocarbon Content (THC)	Solid/liquid extraction and gas chromatography measurement	NF EN ISO 9377-2 ISO 19227 Internal method: FIL-DIJ-MOP-EXP-16001
Medical Devices *(polymer)*	Total hydrocarbon Content (THC)	Solid/liquid extraction and gas chromatography measurement	NF EN ISO 9377-2 ISO 19227 Internal method: FIL-DIJ-MOP-EXP-16001
Medical Devices *(ceramic)*	Total hydrocarbon Content (THC)	Solid/liquid extraction and gas chromatography measurement	NF EN ISO 9377-2 ISO 19227 Internal method: FIL-DIJ-MOP-EXP-16001

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Medical devices	Total organic carbon (TOC)	**Preparation**: Solid/liquid extraction **Detection and quantification**: TOC meter

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical Devices *(metallic)*	Total organic carbon (TOC)	Solid/liquid extraction and determination using TOC meter	NF EN 1484 ISO 19227 Internal method: FIL-DIJ-MOP-EXP-16001
Medical Devices *(polymer)*	Total organic carbon (TOC)	Solid/liquid extraction and determination using TOC meter	NF EN 1484 ISO 19227 Internal method: FIL-DIJ-MOP-EXP-16001
Medical Devices *(ceramic)*	Total organic carbon (TOC)	Solid/liquid extraction and determination using TOC meter	NF EN 1484 ISO 19227 Internal method: FIL-DIJ-MOP-EXP-16001

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Medical devices	Mineral residues	**Preparation:** Solid/liquid extraction **Detection and quantification:** ICP-AES

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical Devices (*metallic*)	Metals: Silver, aluminium, arsenic, barium, beryllium, calcium, cadmium, cobalt, chromium, copper, iron, potassium, lithium, magnesium, manganese, molybdenum, sodium, nickel, total phosphorus, lead, antimony, titanium, vanadium, zinc and zirconium	Solid/liquid extraction and ICP- AES assay	ISO 19227 ISO 10993-12 NF EN ISO 11885 NF EN ISO 10993-18 Internal method: FIL-DIJ-MOP-EXP-18001

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Medical devices	Determination of extraction exhaustiveness	**Preparation:** Solid/liquid extraction **Quantification:** Gravimetry

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices (polymer)	Determination of extraction exhaustiveness using gravimetry	Solid/liquid extraction and analysis of non-volatile residues using gravimetry	ISO 10993-12 Internal method: FILDIJMOP EXP 19003

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Medical devices	Ion compounds	**Preparation:** Solid/liquid extraction **Detection and quantification:** Ion chromatography

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices (metallic)	Chlorides, fluorides, nitrates, bromides, sulphates	Solid/liquid extraction and ion chromatography assay	ISO 10993-12 ISO 10993-18 ISO 19227 Internal method: FILDIJMOP EXP 20006

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES Physical-chemical analyses		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Medical devices	Volatile organic compounds	**Preparation**: Extraction in a solvent **Analysis**: Screening and semi-quantitative or quantitative determination using HS-GC-MS
Medical devices	Semi-volatile organic compounds	**Preparation**: Extraction in a solvent **Analysis**: Screening and semi-quantitative or quantitative determination using GC-MS
Medical devices	Non-volatile organic compounds	**Preparation**: Extraction in a solvent **Analysis**: Screening and semi-quantitative or quantitative determination using LC-MS-QTOF

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices	Volatile organic compounds	Preparation: Extraction in a solvent Analysis: Screening and determination using HS-GC-MS	ISO 10993-12 ISO 10993-18 Internal method: FIL-DIJ-MOP-EXP-21008
Medical devices	Semi-volatile organic compounds	Preparation: Extraction in a solvent Analysis: Screening and determination using GC-MS	ISO 10993-12 ISO 10993-18 Internal method: FIL-DIJ-MOP-EXP-21008
Medical devices	Non-volatile organic compounds	Preparation: Extraction in a solvent Analysis: Screening and determination using LC-MS-QTOF	ISO 10993-12 ISO 10993-18 Internal method: FIL-DIJ-MOP-EXP-21008

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES Physical-chemical analyses			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices (*polymer*)	Accelerated degradation test	Gravimetry	NF EN ISO 10993-13
Medical devices *(ceramic)*	Extreme solution test	Gravimetry	NF EN ISO 10993-14
Implants for surgery - Hydroxyapatite	Heavy metals: Ag, As, Bi, Cd, Cu, Hg, Mo, Pb, Sb, Sn	ICP/MS analysis	NF ISO 13779-3
Medical devices *(metallic)*	Immersion test	Potentiometry	ISO 10993-15
Medical devices *(metallic)*	Identification and quantification of degradation products	ICP/AES analysis	ISO 10993-15
Non-metal powders used for medical devices	Bulk density	Helium pycnometry analysis	ISO 12154

FLEX1 flexible scope: The laboratory is recognised as competent to carry out the tests, in compliance with the referenced methods and their subsequent revisions.

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES Physical-chemical analyses *X-ray characterisation of powders*			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Hydroxyapatite-based powders and coatings	Quantitative Ca/P ratio	X-ray diffraction analysis	NF EN ISO 13779-3
Hydroxyapatite-based powders and coatings	Type and quantity of foreign phases	X-ray diffraction analysis	NF EN ISO 13779-3
Hydroxyapatite-based powders and coatings	Crystallinity	X-ray diffraction analysis	NF EN ISO 13779-3

FLEX1 flexible scope: The laboratory is recognised as competent to carry out the tests, in compliance with the referenced methods and their subsequent revisions.

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical tests			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Foreign bodies such as fibres and particles in medical devices	Identification of foreign bodies and/or contaminants	Sampling or filtration (if suspended in a liquid) Scanning electron microscopy with energy dispersive X-ray spectrometer (SEM + EDX), Micro infra-red Binocular or optical microscope	ISO 10993-12 ISO 10993-19 ISO 10993-22 PE 2.9.52 PE 2.2.24 AAMI TIR 42

FLEX1 flexible scope: The laboratory is recognised as competent to carry out the tests, in compliance with the referenced methods and their subsequent revisions.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical tests		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Medical devices	Number and size of contaminants on membrane	**Sample preparation:** - Extraction via stirring of particulate contamination by immersion or filling the object using extraction solvent - Membrane vacuum filtration **Analysis:** Microscopic count and image analysis

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / MEDICAL DEVICES / Physical tests			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Medical devices (metallic)	Number and size of contaminants on membrane	Extraction via stirring of particulate contamination by immersion or filling the object using extraction solvent Membrane vacuum filtration And microscopic count and image analysis	ISO 10993-12 ISO 10993-19 ISO 19227 USP 788/789 PE 2.9.19 method 2 AAMI TIR 42 Internal method: FILDIJMOP EXP 20005

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS Physical tests		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Medical or pharmaceutical products or solutions for injection	Particle count	**Sample preparation:** Membrane vacuum filtration **Analysis**: Microscopic count and image analysis

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS / Physical tests			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Solution for injection containing an active ingredient	Number and size of particles on membrane	Membrane vacuum filtration and microscopic count and image analysis	USP 788/789 PE 2.9.19 method 2 Internal method: FILDIJMOP EXP 20003

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

General scope

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS / Physical tests		
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**
Raw material or finished product as a solution or powder form	Distribution of size and shape of nanoparticles	**Sample preparation:** Suspension or extraction in a liquid and dispersion on media **Analysis**: Scanning electron microscopy with energy dispersive X-ray spectrometer (SEM + EDX)

FLEX3 flexible scope: The laboratory is recognized as competent in the field covered by the general scope, to adopt any recognized method and to develop any other method for which it has issued validation.

Detailed scope*

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS / Physical tests			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
ZnO/TiO2/BaSO4/Au raw material dispersion and powder	Distribution of size and shape of nanoparticles	Suspension or extraction in a liquid and dispersion on media Scanning electron microscopy with energy dispersive X-ray spectrometer (SEM + EDX)	ISO 10993-22 ISO 19749 Internal method: FILDIJMOP EXP 20002

* The comprehensive list of the accredited methods available is kept up-to-date by the laboratory.

CHEMICAL AND BIOLOGICAL PRODUCTS, MEDICAL EQUIPMENT / BIOCIDES AND HYGIENE PRODUCTS / Physical tests			
SUBJECT	**CHARACTERISTIC MEASURED OR SOUGHT**	**METHOD PRINCIPLE**	**METHOD REFERENCE**
Foreign bodies such as fibres and particles in cosmetic and pharmaceutical products	Identification of foreign bodies and/or contaminants	Sampling or filtration (if suspended in a liquid) Scanning electron microscopy with energy dispersive X-ray spectrometer (SEM + EDX) Micro infra-red Binocular or optical microscope	PE 2.9.52 PE 2.2.24
Suspended or non-suspended multi-scale powder	Specific surface-area analysis	Freeze-drying and/or degassing Measurement by sorptometry (BET method)	PE 2.9.26 ISO 9277
Suspended or non-suspended multi-scale powder	Particle size analysis	Suspended in a solution (if necessary) Liquid or dry laser particle-size analyser	ISO 13320 PE 2.9.31
Non-metal powders for pharmaceuticals or cosmetics	Bulk density	Helium pycnometry analysis	ISO 12154

FLEX1 flexible scope: The laboratory is recognised as competent to carry out 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.*

Granting date: **04/11/2024** Expiry date: **31/10/2025**

This technical annex cancels and replaces technical annex 1-1793 Rev. 22.

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