

Analysis
Qualification
Quantification
Deformation



Medical Devices



PolymEX

ANALYSIS LABORATORY
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RELIABILITY - REACTIVITY

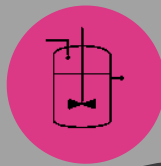
Our services

Polymex owns a wide range of innovative, reliable and efficient equipments to meet all your needs in the field of medical devices :

SAMPLE PREPARATION

ISO 10993-12: 2021

Simulated, exaggerated, exhaustive extract



SURFACE CHARACTERIZATION

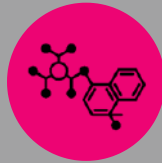
Internal protocol

Detection of stains, traces of pollution, surface appearance, visual defect,...

MATERIALS CHARACTERIZATION

Internal protocol

Establish the composition of materials in case of shortage in information.



CLEANING RESIDUES

ISO 19227/2018 - HCT/COT
(NF EN ISO 9377-2/NF EN 1484)

Confirm cleanliness of devices during cleaning processes.

CHEMICAL CHARACTERIZATION

ISO 10993-18: 2020

Estimation of the potential of the medical device to release chemicals under conditions of clinical use.



ETHYLENE OXIDE RESIDUES

ISO 10993-7: A1-2019

Verification that the rate of Ethylene Oxide (EO) and degradation products (ECH & EG) presents only a minimal risk during use.

Example of service: Characterization of constituent materials

Material composition data not available



1/ Structural study

Determination of the nature of the polymer by Pyrolysis/GCMS and FTIR

2/ Study of additives and adjuvants

Cryogenic grinding for core extraction of the material + VOC/SVOC/NVOC screening

3/ Analysis of other constituents:

Fillers, dyes, pigments

Analytical partner of reference, together we establish a protocol to meet your needs.

Expertise

- * Analytical experts listening to your needs
- * Expertise allowing work in all types of matrices

Normatif

- * Numerous tests under standards
- * In-house development of various analytical methods

Reactivity

- * Average time to send an offer < 1 day
- * Different levels of reactivity in analysis:
 - 10 to 12 working days
 - 5 to 6 working days
 - 2 to 3 days

A laboratory at your service

Polymex is an independent laboratory specializing in the provision of services dedicated to the Study and Expertise of materials and polymers. A know-how of 25 years of experience on analysis, qualification and deformulation.

The laboratory has a complete and efficient analytical park: Pyrolysis/GCMS, GCMS/FID, UPLC/UV/TOF-MS, UPLC/MS/MS, IRTF, SEM/EDX ... The multidisciplinary nature of the equipment allows the laboratory to offer custom analysis in all types of matrices.



Other sectors of activity :



For more information on our laboratory and its skills, do not hesitate to consult the website:

www.polymex.fr

Or contact us directly:

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