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Medical Devices

From compresses to contact lenses, nasal sprays to implants and prostheses, the term ‘medical device’ (MD) encompasses a wide array of products with diverse types and uses. Consequently, medical devices undergo monitoring before, during, and after their market placement.

In the current stringent regulatory landscape, it’s crucial to be well-versed in the key regulations that establish standards for assessing medical devices.

Eurofins companies stand as your Global Testing Partners, providing a range of testing services to facilitate the market launch of your medical device products. Our services encompass analytical chemistry, microbiology, biological evaluation, packaging, utilities, material analyses, electrical safety testing, cyber security, and CE marking.

With over 30 years of expertise in testing medical devices, we boast eight research centers functioning as CRO and CRC to guide you through the various steps of setting up your clinical investigations. Additionally, we have a dedicated center for ex vivo testing.”

Ex vivo testing

Eurofins has developed within its network an ex vivo model of living human skin explants. This model provides solid, reliable evidence of the biological effects of your medical devices on human skin. Ex vivo models particularly suited to :

- R&D pre-clinical testing
- Applicability testing
- Proof-of-concept testing

Directly on plasty and/or explants ± survival (Perfex vivo and ex vivo models)

Some of the claims offered include:

Dermabrasion / Peelings; Healing; Penetration devices; Injectables; Slimming devices; Treatment devices; Tattoo devices…

Clinical investigations

The new Medical Devices Regulation (EU) 2017/745 (MDR) has been fully applicable since 26 May 2021 in order to create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers and healthcare professionals.

Services are performed according to Chapter VI and Annex XV of the Regulation in order to complete your Clinical evaluation report or Post-market Clinical Follow-up. As an accredited and state-of-the-art laboratory, we guarantee total compliance with new requirements of regulation and with ISO standard 14155:2020 (Clinical Investigation of Medical Devices for human subjects – Good Clinical Practice), ethical principles and General Data Protection Regulation standards.

2 types of activity:

- CRO (Contract Research Organization) to support sponsors in the design, implementation and follow-up of their Clinical Investigations in external centers (feasibility study, document writing, regulatory submissions, eCRF preparation, monitoring, statistical analyses, clinical report, scientific publications).
- CRC (Clinical Research Center) with our own investigator sites in various countries (France, Germany, Poland, Tunisia, Romania, Thailand, Mauritius).

Therapeutic areas (non-exhaustive list):

- Dermatology (acne, atopic dermatitis, seborrheic dermatitis, psoriasis, warts, scars, healing, onychomycosis, athlete's foot, ingrown toenails, acrochordons, lice...)
- Aesthetics (wrinkle filling, contour definition, volume, skin quality, scar injections, body injections...)
- Gynecology
- Ophthalmology
- ENT
- Pediatrics
- Proctology
- Podiatry
- Rheumatology
- Physiotherapy etc

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Global Expertise, Personal Touch