Coronati consulting lab

Consultancy and Laboratory Services
for Biomedical Quality

Coronati Consulting is a company certified ISO 9001 and ISO 13485 and accredited by ISO 17025

that offers consultancy services for the development or maintenance of Quality Management Systems in Companies operating in biomedical field, according to the following system rules: ISO 9001 (general), ISO 13485 (biomedical), consultancy activities for CE marking of medical devices and laboratory tests.

LABORATORY TESTS

CONSULTANCY SERVICES

Certified
ISO 9001 and ISO 13485

Accredited by
ISO 17025

Collaboration with Customers Worldwide:

Italy / Germany / Spain / France / Switzerland / Baltic Republic / Croatia
Ireland / Israel / China / England / Turkey / S. Marino Republic

Efficient laboratories for the realization of microbiological, toxicological, chemical, biological and functional tests for the qualification of medical devices

For the realization of sterility tests and microbiological challenge tests, 3 clean room have been set up in class ISO 7 / ISO 5

Over 30 years of experience supporting companies requiring Quality System Certification, CE Marking for Medical Devices, and qualification testing for critical products and processes

OUR MISSION

We are committed to responding to the needs of companies in the medical sector and helping and accompanying them in the certification process by providing effective and advanced solutions.
The services offered are mainly based on the relationship of trust and customer satisfaction.

OUR VISION

Provide reliable, effective and high quality services.
To be a centre of excellence and a leader in the Medical Device sector and perform services to ensure the compliance with the requirements of national and international standards and regulations.

OUR VALUES

Customer satisfaction
Accuracy and competences
Availability and flexibility
Reliability
Impartiality and confidentiality
Punctuality and respect

LABORATORY SERVICES

Coronati Consulting offers a **complete range of laboratory services (Chemical-Microbiological, Biocompatibility and Measurements)** for all classes of Medical Devices: I, IIa, IIb, III. The qualification of the devices, to comply with the requirements of the applicable regulations, is carried out by performing specific laboratory tests according to the most recent applicable standards.

For all classes of Medical Devices I, IIa, IIb, III

Laboratory services

Chemical tests
Microbiological tests
Bio-toxicological tests
Packaging laboratory
Measuring laboratory

CHEMICAL TESTS

- Determination of ethylene oxide residuals: EO-ECH-EG (ISO 10993-7)
- Leachables/extractables ISO 10993-18
- Toxicological risk assessment (ISO 10993-17)
- TOC, THC, Elements and heavy metals (ISO 10993-18 / ISO 19227/ICH)
- Latex protein and Phthalate determination
- Determination of residuals of production process of medical device (e.g. Washing validation)
- Chemical tests according to USP and European Pharmacopeia
- Determination of global and specific migration from plastic materials

MICROBIOLOGICAL TESTS

- Bioburden - (ISO 11737-1 annex B.2 and Annex B.3.1)
- Sterility test on medical device (ISO 11737-2 / Farm. Eur. / USP)
- Sterility test on biological indicators (ISO 11138-1)
- LAL Test (Farm. Eur. / USP)
- Washing process validation
- Evaluation of efficacy cleaning and disinfection/ sterilization of re-usable medical device (ISO 17664, ISO/TS 15883-5, ASTM E 2314-03)
- Microbiological validation of ethylene oxide sterilization (ISO 11135)
- Microbiological validation of moist heat sterilization (ISO 17665-1)
- Microbiological validation of sterilization by irradiation (ISO 11137-1/2)
- Microbiological validation of aseptic processing (ISO 13408-1)
- Microbiological challenge test
- Clean Room validation (ISO 14644-1/2 and UNI EN 17141)
- Particulate contamination in Clean Room (ISO 14644-1)
- Microbiological contamination in Clean Room (ISO 14698-1 and EN UNI 17141)
- Particle count / Particulate matter in injections (USP 788 method 1 – Method 2; ISO 19227; ASTM F 2475; 8536-4)

BIO-TOXICOLOGICAL TESTS

- Biological evaluation of medical device: in vitro and in vivo test required by the ISO 10993-1
- Chemical characterization (ISO 10993-18) and toxicological risk assessment (ISO 10993-17)
- Biocompatibility Evaluation of Medical Device Packaging materials (ASTM F 2475)

PACKAGING LABORATORY

- Accelerated aging at controlled temperature and humidity/temperature (ASTM F 1980)
- Accelerated aging at temperature and humidity controlled (ICH)
- IQ – OQ – PQ packaging validation (ISO 11607-1/2)
- Shipping test (ASTM D 4169 and ISTA Guideline)
- Visual Inspection Test (ASTM F1886-16)
- Measure sealing widths (UNI EN 868-5 Annex D)
- Manual peeling test (UNI EN 868-5 Annex E)
- Sealing strength test (UNI EN 868-5 Annex D)
- Seal strength test (ASTM F 88-F88M)
- Dye penetration Test (ASTM F 1929)
- Dye penetration test (ASTM F 3039-23 Method A)
- Pinholes test on plastic film (UNI EN 868-5 Annex C)
- Microbial barrier of paper (DIN 58953-6)
- Bubble test (ASTM F 2096)
- Burst Strength test (ASTM F 2054M)
- Creep test (ASTM F 1140)

MEASURING LABORATORY

- Instruments calibration (ISO 10012)
- Dynamometric test (pull test and compression)
- Leak test of medical device

OTHER TESTS

- Test on nutrition device (ISO 20695)
- Single use Urethral catheter qualification (ISO 20696)
- Compatibility of ophthalmic solution with contact lenses (ISO 11981)
- Test on infusion device gravity feed (ISO 8536-4)
- Test on hypodermic needle (ISO 7864)
- Test on connectors. Common tests method (ISO 80369-20, ISO 80369-7)
- Intravascular catheter (ISO 10555-1)
- Test on needle/tubes made of stainless steel (ISO 9626)
- Chemical and functional test for transfusion device (ISO 1135-4 and ISO 1135-5)

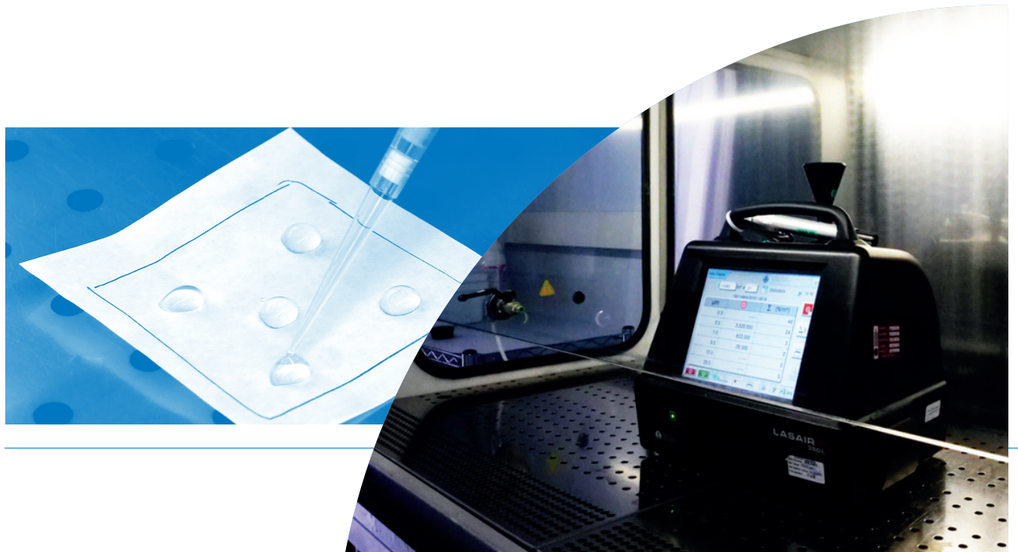
CONSULTANCY SERVICES

Special activities are dedicated to the consultancy for CE marking and Regulatory Affairs for all classes of Medical Devices.

The activities are carried out by **people with appropriate skills and experience** in biomedical and pharmaceutical companies and are submitted to the evaluation of the most important Notified Bodies.

Design and risk analysis

- Assistance during the design of new processes and new medical devices
- Planning of all critical activities
- Identification and interpretation of all applicable standards
- Internal studies, design reviews and release
- Identification of the qualification tests



Consultancy activities for CE Marking and quality system

- Regulatory strategy definition
- BEP_Biological Evaluation Plan (ISO 10993-1)
- BER_Biological Evaluation Report (ISO 10993-1)
- Toxicological risk Analysis according to ISO 10993-17
- Gap analysis
- Laboratory testing and process validation management
- Protocols for test and process validations
- Support for the resolution of non-compliances
- Technical Documentation for CE marking of Medical Devices
- Risk Analysis and Risk Management according to ISO 14971
- Clinical evaluation report (UE Regulation 745:2017)
- Safety and Performance Check list (UE Regulation 745:2017)
- Registration Medical Devices at the Italian Ministry of Health
- Preparation of technical and personalized documents

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Coronati Consulting Srl
Via L. Gavioli, n. 3 - 41037 Mirandola (MO)
Tel. 0535.611533 - Fax 0535.410441
info@coronaticonsulting.it
www.coronaticonsulting.it

List of accredited test

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