



IMQ MED-TECH HUB

CERTIFICATION, INSPECTION & TESTING

TO SUPPORT YOUR COMPLIANCE CHALLENGES



**OUR ENGINEERS'
GOAL?
TO ENHANCE
THE QUALITY OF
YOUR PRODUCTS**



OUR EXPERIENCE TO SUPPORT YOUR COMPLIANCE CHALLENGES

30 years of experience in testing medical devices and the obtained accreditations, make IMQ a center of excellence offering testing and certification recognised **throughout the world**.

We provide active and non-active medical device manufacturers with a complete offering of third-party regulatory approvals, product testing and certification, auditing, cybersecurity testing, usability testing, and the training to support your compliance challenges.

PRODUCT CERTIFICATION

Export to European Union Regulation (EU) 2017/745 (MDR).

The MDR lays down rules concerning the placing, making available and putting into service on the EU market the following devices:

- Medical devices for human use and their accessories
- Products that are not intended for medical use listed in Annex XVI of the MDR.

 **IMQ is Notified Body for the
Regulation (EU) 2017/745 (MDR)**

MAIN PRODUCTS CERTIFIED

- Active and Non active Medical Devices
- Active Implantable Medical Devices
- Radiology Devices
- Software and AI
- Medical Devices substance based
- Annex XVI Devices – without medical intended use





MDSAP Auditing

**Exporting worldwide:
5 countries, one unified
audit.**

IMQ is recognised as an Authorised Auditing Organization for MDSAP (*Medical Device Single Audit Program*), the program that allows medical device manufacturers to verify with a single audit (instead of 5) compliance with the Quality System Management Requirements (*GMP: Good Manufacturing Practice*) required to be able to export electromedical equipment to the **USA, Canada, Brazil, Japan and Australia.**



PRODUCT TESTING

(electromedical, non-active, packaging)



OUR TESTS ARE AIMED
TO FIND OUT ANY FAULT
THAT MIGHT COMPROMISE
THE RELIABILITY
OF YOUR PRODUCTS.



From radiology devices to a humanoid, from medical equipment packaging to the most advanced artificial intelligence devices and medical robots, we can test each of your products, according to the main international standards.



In general, we can test medical devices, esthetic equipment, laboratory machinery, veterinary equipment, ...



- » **ELECTRICAL SAFETY**
- » **EMC**
- » **FUNCTIONALITY**
- » **COMMUNICATION WITH OTHER DEVICES**
- » **CYBERSECURITY**
- » **BIOCOMPATIBILITY**

For non-active devices: chemical characterization; in vitro irritation; sterilization validation; toxicological evaluation.

For packaging: transit simulation - packaging performance; accelerated ageing of sterile medical device packages; validation of sterile barrier system.

More than 20,000 m² of accredited laboratories to the main international standards, five EMC chambers (one of which is among the largest in Europe with measurement capabilities up to 10 metres), confirms **IMQ as one of the major European poles for one-stop service of verification and certification of the most innovative products.**

WHY TEST YOUR PRODUCTS AT IMQ?

**SOME
“ACCREDITED”
REASONS WHY
YOU SHOULD**





More than 30 years of experience

in testing medical devices and the obtained accreditations, make IMQ a center of excellence offering testing and

Accredited Laboratory ISO 17025

(IEC/EN 60601, IEC/ISO 80601,
IEC/EN 61010, ...)



LAB N° 0121 L

CB Certificates

Testing Laboratory & Certification Body Recognised

Reg. EU 2017/745 Notified Body

MDSAP Inspection Authorised Auditing Organization

Technical partner of the market surveillance
Authorities

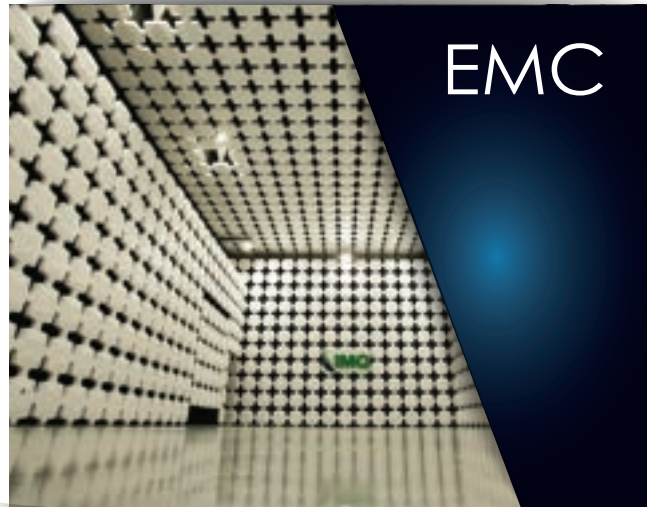
OUR LABS



IMQ Safety Lab (Milan)
(ACCREDIA - CBTL)

IMQ Health & Wellness Lab (Bollate - MI)

TEST ON ELECTROMEDICAL DEVICES, ELECTRIC VETERINARY DEVICES, BEAUTY EQUIPMENT



IMQ EMC Lab (Milan)
(ACCREDIA - CBTL)

IMQ 10 m semianechoic chamber
(Bollate - MI)
(ACCREDIA - CBTL)

- DIMENSIONS: 20.5 M (L) x 10.6 M (W) x 8.3 M (H)
- SLIDING DOOR OF 3x3.5 METRES & TILTING PLATFORM
- MEASURING DISTANCE: UP TO 10 METRES
- RADIATED EMISSIONS: 150 kHz - 40 GHz
- IMMUNITY TESTS: 20 MHz - 18 GHz
- ROTARY TABLE: 5 M; CAPACITY 6 TONNES



Quality Lab
c/o CSI (Bollate - MI)

- CHEMICAL-PHYSICAL CHARACTERISATION
- BIOCOMPATIBILITY
- TRANSPORT SIMULATION
- PACKAGING VALIDATION
- MICROBIOLOGICAL TEST
- STERILITY TESTING



ABOUT IMQ GROUP

IMQ is one of Europe's top players in the field of conformity assessment.

Our experience comes from working closely with manufacturers, businesses, organisations and service providers operating in a wide range of sectors.

All this translates into a major benefit for our customers because it gives them an authoritative partner, with extensive experience, that is a technical consultant to ministries and public authorities on matters of auditing to ensure properly regulated markets, that has top-quality staff and is a member of the main working groups on international standards.

The IMQ Group is currently composed of a holding company (IMQ Group S.r.l.) and 12 operating companies, five of which in Italy - IMQ S.p.A., CSI S.p.A., IMQ Intuity S.r.l, IMQ Minded Security S.r.l., IMQ eAmbiente S.r.l. - and seven abroad: IMQ Certification (Shanghai) Co. Ltd. (China), IMQ Certification (UK) Ltd. (United Kingdom), IMQ CSI Deutschland GmbH (Germany), IMQ Gulf FZCo (United Arab Emirates), IMQ Iberica S.L. (Spain), IMQ Polska Sp. z o.o. (Poland), IMQ Turkey (Turkey).



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