ABOUT US

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.

IMQ is an IMQ Group Company, one of Europe's top players in the field of conformity assessment, with over 70 years of experience.

IMQ is Notified Body for the Regulation (EU) 2017/745 (MDR), Accredited Laboratory ISO 17025, CB Certificates Testing Laboratory & Certification Body Recognised.

IMQ is also accredited to certify management systems in accordance with ISO standards and is the only Italian organisation recognized as an **authorized MDSAP Auditing Organisation.**

The biocompatibility tests are carried out in the laboratories of CSI S.p.A. (another IMQ Group Company) and are covered by specific ISO 17025 accreditation. Additionally IMQ qualifies CSI as its own testing laboratory through internal procedures.

The reliability and transparency of the results is guaranteed by our state-of-the-art equipment and the expertise our technicians have acquired from their experience, continuous updating and membership of the main working groups on international standards.

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BIOCOMPATIBILITY TESTS:

Chemical characterization and toxicological risk assessment

What are the regulatory requirements for medical devices?

Regulation (EU) 2017/745:
- GSPR n. 10
- Annex II paragraph 6.1.b

Relevant technical standards:
- ISO 10993-1:2018
- ISO 10993-18:2020
- ISO 10993-17:2023
- ISO 10993-12:2021

What can chemical characterization and toxicological risk assessment be used for?

- Screening new materials for suitability;
- Support the demonstration of the mechanism of action (e.g. substance-based medical devices);
- Minimizing animal use and reducing the costs for the other tests of biocompatibility as suggested also by the European Commission;
- Demonstrating biological equivalence – fundamental requirement for active and non-active medical devices. All the devices with parts in contact with human bodies must take in consideration these tests for the biological evaluation of the device and its material to satisfy the MDR requirements.

What can IMQ provide?

DESCRIPTION	REFERENCES
GC-HS: characterization - volatile compounds (screening untarget)	ISO 10993-18:2020 ISO 10993-12:2021
GC-MS: characterization - semi-volatile compounds (screening untarget)	ISO 10993-18:2020 ISO 10993-12:2021
LC-QTOF: Organic additives (MW>800)	ISO 10993-18:2020 ISO 10993-12:2021

The following output are provided: Retention time; CAS #; Concentration (µg/ml).

ICP-MS: elemental analysis (metals screening) — ISO 10993-18:2020 ISO 10993-12:2021

Determination of metals through ICP-MS. The quantification is performed through an external calibration of metals in the same simulant solutions:

Li - LOQ: 0.1 µg/l	Mn - LOQ: 0.1 µg/l	Ag - LOQ: 0.1 µg/l
Be - LOQ: 0.1 µg/l	Fe - LOQ: 5 µg/l	Cd - LOQ: 0.1 µg/l
B - LOQ: 10 µg/l	Co - LOQ: 0.1 µg/l	Sn - LOQ: 1 µg/l
Mg - LOQ: 10 µg/l	Ni - LOQ: 0.1 µg/l	Sb - LOQ: 1 µg/l
Al - LOQ: 2 µg/l	Cu - LOQ: 1 µg/l	Ba - LOQ: 1 µg/l
Ti - LOQ: 1 µg/l	Zn - LOQ: 1 µg/l	Hg - LOQ: 0.2 µg/l
V - LOQ: 0.1 µg/l	As - LOQ: 0.1 µg/l	Tl - LOQ: 0.01 µg/l
Cr - LOQ: 0.1 µg/l	Mo - LOQ: 0.1 µg/l	Pb - LOQ: 0.1 µg/l

Toxicological risk assessment of medical device constituents — ISO 10993-17:2023

Toxicological risk assessment, including determination of:

- Toxicological Screening Limit (TSL);
- Worst case Estimated Exposure Dose (EEDmax);
- Tolerable Intake (TI);
- Threshold of Toxicological Concern (TTC);
- Margin of Safety (MOS).

Evaluation performed by qualified toxicologists.

PVC based materials - phthalates — European Pharmacopoeia 11 3.3.2 - 3.3.3

- Content of phthalates: DEP-DOP/DEHP-DNOP-DBP-DBPiso-BTP-BBP-DIHP-DIDP-DINP-DCH, through extraction and subsequent gas cromatographic analysis;
- Bisphenol A (limit 0,03 µg/ml). Simulants: Water and acetic acid 3% in water.

Chemical Residuals Analysis — USP 643 - USP 467

- Surfactant residuals (cationic, anionic, non-ionic), manufacturing mineral oils;
- Total Organic Carbon (TOC);
- Residual solvents.