

Surface characterisation

A CE Mark certificate is needed in order to market a medical device in the EU. This certificate verifies that the product is safe and performs as intended. The *ISO 10993-1* standard prescribes a process for designing, testing, and documenting the biological safety of a medical device product.

Both implanted medical devices and medical devices that come into contact with circulating blood must undergo a physico-chemical, morphological, and topographical (PMT) characterisation in order to document compliance with regulatory requirements, including: shape and form, morphology, topography, surface chemistry, etc.

SAXOCON provides you with everything you need to document compliance with regulatory requirements including:

- Measurements of physico-chemical, morphological, and topographical properties according to *ISO 10993-19:2020*
- Documentation and presentation of results
- An overall risk assessment of the device

Why choose us?

SAXOCON analytical services for nanomaterials give you access to:

- Extensive expertise in measurement and characterisation of materials and surfaces
- A multidisciplinary team of highly skilled scientists and experts
- High-level experience in state-of-the-art toxicological evaluations according to international standards

Delivery

SAXOCON generates and compiles all physical characterisation data needed to support the biological evaluation of your product.