

## 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 physicochemical, 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 physicochemical, 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 with 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.