

Declaration of Interest



The notified body TÜV NORD CERT GmbH (TN CERT) is acting as an independent third-party certification and conformity assessment body for medical devices covered under the accredited and designated scopes.

As notified body TN CERT follows the regulations stipulated in the (EU) 2017/745, operates its activities and maintains a system based on documented procedures within its organization that safeguards impartiality, objectivity and independence of all activities as well as the personnel involved.

TN CERT offers its services to all interested parties after detailed review of the submitted applications and without preference or discrimination.

We as the managers of TN CERT are not engaged in any activity that may jeopardise independence of judgement or integrity in relation to certification and conformity assessment activities under designation nor accreditation.

We as the managers of TN CERT are neither involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the medical devices for which TN CERT is designated, nor do we represent the parties engaged in such activities.

We as managers of TN CERT do neither provide consultancy in the field of accreditation and designation scopes nor is linked to an organization which itself provides consultancy services.

We as the top-level management and the personnel responsible for carrying out the conformity assessment tasks are neither designer, manufacturer, supplier, installer, purchaser, owner or maintainer of the devices assessed, nor are they authorized representatives of these groups. The restriction shall not preclude the purchase and use of assessed medical devices necessary for the operations or the performance of conformity assessment, or the medical devices for personal use.

The level of remuneration for us as the management and of the personnel responsible for carrying out the conformity assessment tasks involved in assessment activities does not depend on the results of the assessments.

We avoid any potential conflict of independence, interest or impact to the impartiality and objectiveness during the certification and conformity assessment procedures, all applications from potential customers such as but not limited to manufacturers, other economic operator or competitors of the manufacturer - which does not preclude TN CERT from performing certification or conformity assessment to competing manufacturer, an initial application assessment is performed prior to any further activity.

TN CERT is not owned by a public entity or institution.

TN CERT hereby makes the declaration of interest publicly available.