



**Add value.
Inspire trust.**

MDR/IVDR Declaration of Interest

Ensure quality at the heart of your operations.

The Board of Management of TÜV SÜD Product Service GmbH declares the following on behalf of the entire Top Management:

As a Notified Body, we carry out all testing, certification and conformity assessment activities and the associated controls based on our [Testing, Certification, Validation and Verification Regulations \(TCVVR\)](#) as a third party with the highest professional integrity and the necessary expertise.

To ensure independence, impartiality and objectivity, we only provide testing and certification services under the MDR and IVDR after submitting a conformity assessment application. With regard to potential conformity assessment procedures under the MDR and IVDR, we generally do not offer any consulting services, neither for our customers nor for economic operators, which go beyond the exchange of technical data and regulatory guidelines.

The testing and certification services are made available to all interested parties without any favoritism or discrimination after scrutinising the applications. Impartiality, as an important and exclusive element, is always guaranteed; in particular, care is taken to ensure that commercial, financial, private or other pressures do not jeopardise impartiality.

Our employees make all testing and certification decisions based solely on legal or regulatory, technical or normative requirements and follow the [TÜV SÜD Code of Conduct](#). We guarantee the impartiality of the Notified Body, Top Management and assessment staff. The level of remuneration of the Top Management and the assessing staff of the Notified Body and the subcontractors involved in assessment activities does not depend on the results of the assessment.

All members of the Top Management of the Notified Body have also personally committed themselves to vouching for compliance with the above principles and have also committed themselves to the following declaration of interests to confirm their personal independence:

“My independence as a member of the Top Management of the Notified Body for medical devices and in vitro diagnostics is not affected by any personal financial interests. I do not hold shares, stocks, bonds or investment certificates, and/or assets and/or liabilities in companies to be audited or certified. Excluded from this is ownership of shares or other ownership interests in collectively managed funds whose portfolio I have no influence on, as well as ownership of shares or other ownership interests whose management has been transferred to a third-party manager over whom I have no influence on the investment decisions.

My remuneration is not dependent on the number of conformity assessment activities carried out by the Notified Body, nor on the results of this activity.”

TÜV SÜD Product Service GmbH

Signed: Wolfgang Hübl (CEO TÜV SÜD PS GmbH)

Signed: Patrick van Welij (CFO TÜV SÜD PS GmbH)

Signed: Karl Meier (COO TÜV SÜD PS GmbH)

Signed: Dr. Andreas Stange (SVP MHS Regulatory & Quality)

Signed: Dr. Royth von Hahn (SVP MHS Business Unit Manager)

Signed: Dr. Christoph Lindner (Business Unit Manager MHS Germany)

Related services

TÜV SÜD provides the following related services:

- Medical Device Market Approval & Certification
- Medical Devices and IVDs Testing
- Quality Management and Quality Control for Medical Devices