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MDR Declaration of Interest and Commitment to Impartiality – NB 2443

1. Role as Notified Body

TÜV SÜD Danmark ApS, acting as a Notified Body in accordance with Regulation (EU) 2017/745 for Medical Devices (MDR), performs conformity assessment and certification activities as an independent third-party organisation.

All activities are conducted in accordance with relevant MDR requirements and supported by the [TÜV SÜD Group Testing and Certification Regulations](#), ensuring consistent governance, professional integrity and technical competence.

2. Application and Scope of Certification Activities

To safeguard independence, impartiality and objectivity, TÜV SÜD Danmark ApS provides certification services exclusively following the formal receipt and acceptance of a conformity assessment application under MDR.

3. Consultancy Prohibition and Organisational Separation

TÜV SÜD Danmark ApS, as an affiliated company of TÜV SÜD AG, confirms that neither the Notified Body nor affiliated TÜV SÜD entities offer or provide consultancy services related to the design, construction, marketing or maintenance of devices or processes to customers, its authorised representatives, suppliers or commercial competitors in the field of medical devices.

When exchanging information we ensure full compliance with MDR requirements.

4. Impartiality and Independence

TÜV SÜD Danmark ApS acts impartially and performs all conformity assessment activities without favouritism, discrimination or undue influence.

Organisational structures, decision-making processes and internal controls ensure that commercial, financial or other pressures do not compromise independence, impartiality or objectivity.

5. Personnel and Ethical Conduct

All employees and external personnel involved in conformity assessment activities base their evaluations and decisions solely on applicable legal, regulatory, technical and normative requirements.

These activities are performed in strict adherence to the [TÜV SÜD Code of Conduct](#) and internal impartiality policies.

6. Remuneration and Safeguards

The impartiality of the Notified Body, its Top-level Management and all personnel involved in conformity assessment activities is safeguarded through defined organisational measures.

The remuneration of Top-level Management, assessment personnel and subcontractors is independent of the number, outcome or commercial success of conformity assessment activities.

7. Declaration of Interests of Top-level Management

All members of the Top-level Management of the MDR Notified Body formally declare their independence and freedom from conflicts of interest.

In particular, they confirm that they hold no financial interests that could influence judgment and decisions, that their remuneration is not linked to the volume or outcome of assessments, and that they are not linked to organisations providing consultancy services to customers, authorised representatives, suppliers or commercial competitors within the medical device industry.

8. Public Availability and Commitment

The undersigned members of the Top-level Management of TÜV SÜD Danmark ApS have formally committed to uphold these principles at all times.

The Notified Body makes this Declaration of Interest publicly available in accordance with Annex VII 1.2.5 of MDR to ensure transparency and maintain stakeholder confidence.

Date: 02/26/2026

Members of the Top-level Management of TÜV SÜD Danmark ApS –
Notified Body 2443:

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

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

Signed: Lars H. Brockhoff (CEO TÜV SÜD Danmark ApS)

Signed: Martin Jakobsson (Vice President, TÜV SÜD Denmark MHS)

Signed: Malou Hjørnesen (Head of Notified Body)