

Declaration of Interests

To ensure independence, impartiality and objectiveness, we provide conformity assessment activities services under the scope of the MDR. We do not offer consulting services either to economic operators or to our customers other than exchange of technical information and regulatory guidance.

Our conformity assessment activities services are offered to all interested parties after detailed review of the submitted applications and without preference or discrimination.

We always ensure impartiality as an important and exclusive element; in particular, we make sure that our impartiality is not jeopardized by any commercial interests, financial interests, private interests or any other pressure.

Our employees make all conformity assessment activities decisions solely in line with the legal or regulatory, professional or normative requirements and following the TÜV SÜD Code of Conduct.

We guarantee the impartiality of the notified body, the management team, the conformity assessment and administrative personnel. The level of remuneration of the management team and assessment personnel of the notified body and of any subcontractors involved in assessment activities does not depend on the results of the assessments.

By signing this declaration I declare as top management of TÜV SÜD Danmark ApS not to:

- a) be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorized representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;
- b) be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which TÜV SÜD Danmark ApS are designated, nor represent the parties engaged in those activities;
- c) engage in any activity that may conflict with independence of judgement or integrity in relation to conformity assessment activities for which TÜV SÜD Danmark ApS is designated;
- d) offer or provide any service which may jeopardize the confidence in TÜV SÜD Danmark ApS independence, impartiality or objectivity. In particular, TÜV SÜD Danmark ApS shall not offer or provide consultancy services to the manufacturer, its authorized representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment, and
- e) be linked to any organization which itself provides consultancy services as referred to in point (d). Such restriction does not preclude general training activities that are not client specific and that relate to regulation of devices or to related standards.
- f) Have any personal interest or having relatives that to my knowledge has any interest such as ownership, financial investments or company shares in any medical device



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companies, or medical device distributors, which might jeopardize independence, impartiality or objectiveness.

With signing this declaration, I declare that TÜV SÜD Danmark ApS as Notified Body performs all its conformity assessment activities as a third party applying the highest degree of independence, impartiality and objectiveness.

Name and title:

Lars Henrik Brockhoff
CEO, TÜV SÜD Danmark ApS

Place: Copenhagen

Signature: