

Declaration of Impartiality, Independence, and Handling of Confidential Information

In this statement, the management of NoBoMed Zrt. commits itself to impartiality, independence, and confidential handling of information.

NoBoMed Zrt. conducts its conformity assessment activities impartially and in compliance with the requirements of the **(MSZ) EN ISO/IEC 17021-1:2016** standard and the Regulation **(EU) 2017/746** which regulates the placing on the market of in vitro diagnostic medical devices .

To ensure impartiality, NoBoMed Zrt.:

- in order to ensure its legal identifiability, displays its name, address, and other contact information on its letterhead and on all documents issued by it as a certification body under ,
- as a certification/conformity assessment body, declares its impartiality to ensure confidence in the documents it issues,
- remains independent from its clients and other parties in relation to its activities of certification/conformity assessment, is responsible for the impartiality of its activities, and does not allow commercial, financial, or other means to be used to pressure it into compromising its impartiality,
- NoBoMed Zrt. ensures its impartiality by that the compensation levels of its senior management and the staff conducting the evaluations do not depend on the results of the evaluations, and clients of this are informed in advance,
- the owner, and the organization's senior management – that is, the members of its board of directors of NoBoMed Zrt. – are aware of the independence and impartiality requirements imposed on them; they submit a declaration of interests and NoBoMed Zrt. publishes on its website the text of the declaration and the names of the individuals concerned,
- NoBoMed Zrt. performs conformity assessment activities as an independent third party, free from influence by the device manufacturers, economic operators with an interest in the device, and the manufacturer's competitors ,
- NoBoMed Zrt. impartial and financially independent, and its management and staff are not subject to any commercial, financial, or other interests that would compromise the independence, impartiality, and objectivity of their conformity assessment activities,
- NoBoMed Zrt. operates a quality management system within the framework of which it has established an organizational structure and operates in a manner that guarantees the independence, objectivity, and impartiality of its conformity assessment activities. Within the framework of the quality management system, procedures have been implemented that proactively and effectively ensure the identification, investigation, and resolution of any cases in which a conflict of interest arises, including:
 - participation in consulting services related to medical devices prior to employment at NoBoMed Zrt., previous employment with a manufacturer concerned, or other causes of conflict of interest,
 - annual monitoring of the declarations of interest submitted by the owner and the members of the Board of Directors,
 - proactive verification of clients and experts involved in a given project, as well as ensuring the independence from one another of those who are involved in conducting certification/conformity assessments and decision-preparation and decision-making mechanisms,
 - annually assesses the effectiveness of its measures to ensure independence and impartiality through its risk management processes, internal audit and management review with involving interested parties in the process by consultation when necessary,

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- All members of its staff who may influence certification activities act impartially and do not yield to any commercial, financial, or other pressure that could compromise their impartiality;
- requires its employees to report any situation that comes to their attention that could constitute a conflict of interest for them or for NoBoMed Zrt.,
 - monitors, analyzes, and documents conflicts of interest arising from certification decisions, including those arising from other existing relationships with the client,
 - if a relationship jeopardizes impartiality, it shall not undertake the certification,
 - it does not provide consulting services or conduct training for manufacturers, their suppliers, or their subcontractors,
 - it does not certify any system where a relationship between the consulting organization involved in its development and NoBoMed Zrt. compromises impartiality,
 - does not involve subcontractors in certification/conformity assessment activities, so that they cannot influence the independence, impartiality, or objectivity of conformity assessment activities.

To ensure impartiality, NoBoMed Zrt., its owner, the members of its board of directors, the management, and the staff responsible for performing its conformity assessment activities of the system certification body, in full awareness of their responsibilities, declare:

- it is not the designer, manufacturer, supplier, installer, purchaser, owner, or maintainer of the device it has assessed, nor is it an authorized representative of any of these parties. This restriction does not preclude the purchase and use of assessed devices necessary for the operation of NoBoMed Zrt. or for the performance of conformity assessment, nor does it preclude the use of such products for personal purposes,
 - shall not participate in the design, manufacture, or production, placing on the market, putting into service, or use or maintenance of devices for which they have been designated, and shall not represent parties involved in such activities,
 - does not engage in activities that could compromise the independence or integrity of decision-makers in relation to the conformity assessment activities for which they have been designated,
 - does not offer or provide any service that could undermine confidence in their independence, impartiality, or objectivity. In particular, they shall not offer or provide consulting services to the manufacturer, the manufacturer's authorized representative, suppliers, or commercial competitors regarding the design, manufacture, marketing, or maintenance of the devices or procedures subject to evaluation, nor
 - is not affiliated with any organization that provides the consulting services mentioned in the preceding paragraph. These restrictions do not preclude general training activities that are not client-specific and are related to the regulation of devices or to standards.

NoBoMed Zrt. conducts its certification/conformity assessment activities in accordance with the requirements of applicable laws and standards; the description of the certification/conformity assessment process is publicly available for the clients, and the terms and conditions are set forth in the contract.

In the spirit of transparency, we publish our fees on our website, and we take into account the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC.

Any manufacturer applying for certification / conformity assessment may access NoBoMed Zrt.'s services without restriction or other conditions, unless NoBoMed Zrt.'s identifies any potential conflicts of interest, provided that the request falls within the organization's territorial scope of operation and meets the language requirements, and NoBoMed Zrt. holds accreditation / designation for conformity assessment activities in the requested field, which information is available on the website to all interested parties.

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NoBoMed Zrt. ensures that its organization and the staff respect the confidentiality of information that comes into their possession during the performance of certification / conformity assessment activities, unless disclosure is required by law.

The staff of NoBoMed Zrt. shall respect the rules of professional confidentiality during certification/conformity assessment activities, except when communicating with the authorities responsible for notified bodies, the competent Member State authorities responsible for medical devices, or the Commission. NoBoMed Zrt. respects the ownership rights of its clients' intellectual property and material assets.

Budapest, 2026.06.08.

Dr. Csilla Pozsgay m.p.
Chair of the Board of Directors
NoBoMed Zrt.