



Declaration of Interest of the Top Management of NB 1023

NB 1023's top management issues this Declaration of Interest of NB 1023's top management of the Institute for Testing and Certification, Inc. (hereinafter referred to as "ITC"), and makes it also publicly available with respect to the requirement set forth in Annex VII, section 1.2.5. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter "MDR").

NB 1023 has made great strides in the quality of conformity assessment of medical devices while increasing the level of accountability of medical device manufacturers for their products. It is also evident that NB 1023 has been and is able to respond adequately to medical device safety requirements, as despite the strict conditions of surveillance and assessment controls, no case has yet been identified where NB 1023 has issued a certificate for a medical device that is unsafe or endangers the health of patients.

It is the interest of the top management of NB 1023 within the meaning of Article 1.1.6 of Annex VII of the MDR to carry out the conformity assessment activities of the notified body in accordance with the MDR and related legislation.

The top management of NB 1023 takes its position and responsibility in the medical device conformity assessment system very seriously.

It is sensitive and keenly aware of the need to increase the requirements for conformity assessment of medical devices, including increasing the requirements for professional and technical competence, independence and impartiality of NB 1023.

The common interest of all persons involved in conformity assessment in NB 1023 is, in particular, the safety and effectiveness of medical devices placed and marketed and the safety of patients and users of these devices.

The top management of NB 1023 declares:

1. The commitment to independence and impartiality is seen as one of the most important aspects to ensure confidence in the conformity assessment activities of NB 1023. The conformity assessment of medical devices in NB 1023 is and will continue to be organized and implemented in such a way as to guarantee independence, objectivity and impartiality in the conformity assessment activities in NB 1023.
2. It shall have an organisational structure and operate in such a way as to ensure independence, objectivity and impartiality in conformity assessment activities for medical devices.
3. It shall not use any means to compromise independence and impartiality in NB 1023 conformity assessment activities;
4. It has applied and will continue to apply a mechanism to ensure that management and others involved in the conformity assessment of NB 1023 medical devices are free from any undue commercial, financial or other internal or external pressures that could adversely affect their judgement.
5. It has created and will continue to create the conditions for the performance of NB 1023 activities as a third-party entity that is independent of the economic operator that has an interest in the conformity assessment of the product, service or system in NB 1023 and is also independent of any competitor of that economic operator.
6. NB 1023 has, and will continue to have, procedures in place to effectively ensure the identification, investigation and resolution of any case where a conflict of interest may arise and the impartiality and/or independence of the NB 1023 conformity assessment is compromised.
7. NB 1023 has and will continue to have procedures in place to ensure that its top management and personnel responsible for performing medical device conformity assessment tasks:

- are not the designer, manufacturer, supplier, installer, purchaser, owner, or maintainer of the equipment they are assessing, or an authorised representative of any of these parties;
 - have not been involved in the design, manufacture or construction, marketing, installation and use or maintenance of the equipment for which they are appointed, nor have they represented parties engaged in those activities;
 - they have not carried out any activity that could compromise their independent judgement and integrity in relation to the conformity assessment activities they are appointed to carry out;
 - not provide or offer any services that could undermine confidence in their independence, impartiality or objectivity, in particular advice to the manufacturer, its authorised representative, supplier or commercial competitor on the design, construction, marketing or maintenance of the devices or on the procedures being assessed;
 - are not affiliated to any organisation which itself provides consultancy services as referred to in the previous paragraph.
8. We will ensure that involvement in the provision of advisory services prior to employment with ITC is fully documented in NB 1023 at the commencement of employment and potential conflicts of interest are monitored and addressed in accordance with the requirements of Annex VII of the MDR.
 9. We will ensure that personnel who were originally employed by or provided resource advisory services to a specific client are not assigned to conformity assessment activities relating to that specific client or companies belonging to the same group within the meaning of § 79 of Act 90/2012 Coll. on Business Corporations, as amended, for a period of three years.
 10. We have and will continue to strictly adhere to the principle that the amount of remuneration of NB 1023's top management, NB 1023's conformity assessment personnel and, where applicable, subcontractors involved in conformity assessment activities, is independent of the results of the assessment.
 11. We will respect the proposals and binding opinions of the ITC Impartiality Assurance Commission, issued in accordance with applicable and effective laws and standards, regarding the assurance of impartiality of decision-making of the ITC conformity assessment body.
 12. We will continue to provide professional development for staff involved in conformity assessment in NB 1023.
 13. NB 1023 has adequate resources for conformity assessment activities and NB 1023 top management will not allow donations to fund NB 1023 conformity assessment activities.

In Zlín on 11th November, .2021

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Mgr. Jiří Heš
 Director General of ITC

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Ing. Pavel Vanek
 Director of Certification
 Division

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Ing. Pavla Heinzová
 Deputy Director of the
 Medical Device
 Certification Division

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Ing. Tomáš Závisek
 Head of the Medical
 Device Certification
 Department