



Declaration of Commitment of Impartiality of NB2265 Top Management

NB2265 Top Management hereby declares:

1. The quality policy and procedures described in the NB2265 Quality manual are applied during the performance of MD / IVD MD conformity assessment and are not discriminatory.
2. All applicants have access to NB2265 services without any restrictions or other conditions.
3. NB2265 is impartial, financially independent and its management and personnel are not under the influence of commercial, financial or other interests that could compromise the independence, impartiality and objectivity of the MD / IVD conformity assessment activities for which it is designated and notified.
4. NB2265 acts as a third party independent of the manufacturer of the products that are subject to the MD / IVD MD conformity assessment activities. NB2265 is also independent from all economic subjects with are interested in the device as well as from all competitors of its manufacturer.
5. NB2265 has such an organized structure and operates in such a way as to guarantee the independence, objectivity and impartiality of its activities. It disposes with established procedures that effectively ensure the detection, investigation and resolution of all cases of potential conflicts of interest, including the participation of its staff in advisory activities within the field of MD / IVD MD before they become employees of NB2265.
6. NB2265, its top management and personnel responsible for carrying out the MD / IVD MD conformity assessment tasks:
 - a) are not a designer, manufacturer, supplier, installer, purchaser, owner or maintainer of the MD / IVD MD which they assess, nor the authorised representative of any of those parties. Such restriction does not preclude the purchase and use of the assessed MD / IVD MD that are necessary for the operations of the notified body and the conduct of the conformity assessment or the use of such MD/ IVD MD for personal purposes;
 - b) are not involved in the design, manufacture or construction, marketing, installation and use or maintenance of the MD / IVD MD for which they are designated, nor represent the parties engaged in those activities;
 - c) are not engaged in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities of the MD / IVD MD for which they are designated;
 - d) do not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they do not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment, and
 - e) are not linked to any organization which itself provides consultancy services as referred to in point (d).

Such a restriction does not preclude general training activities that are not client specific and that relate to legislation on MD / IVD MD or to related standards.
7. The top management of NB2265 and its personnel performing conformity assessment of MD / IVD MD are impartial. The level of remuneration of the top management and employees of NB2265 and any subcontractors performing the assessment does not depend on the results of the assessments.
8. NB2265 has a MD / IVD MD Conformity Assessment Board and a Committee for the Protection of Impartiality, which includes representatives of those parties concerned by the certification scheme and are independent and impartial.
9. NB2265 shall ensure that the activities of its potential subsidiaries or subcontractors or of any subject with which it has a relationship, including the activities of its owners, do not affect the independence, impartiality or objectivity of the conformity assessment activities it carries out.
10. NB2265 and its staff are not engaged in any activities that could undermine confidence in the conformity assessment process and compliance with moral and ethical principles.



Declaration of Commitment of Impartiality of NB2265 Top Management

11. NB2265 performs all activities within the MD / IVD MD conformity assessment in accordance with the requirements of legislation and applicable standards and within the scope of its designation and notification so as not to raise objections or distrust of the granted certification in the MD / IVD MD conformity assessment process, taking into account the interests small and medium-sized enterprises as defined in Recommendation 2003/361/ES regarding fees. All employees of NB2265 who participate in the MD / IVD MD conformity assessment process, are acquainted with the wording of currently valid documents and these documents are commonly available.
12. Requirements, evaluations and decisions of NB2265 are limited to clearly defined and contractually confirmed MD / IVD MD in all phases of the MD / IVD MD conformity assessment process.
13. NB2265 has permanent internal and external personnel reporting to the Director of NB2265 / Deputy Director of NB2265. We have personal responsibility for the activities performed in the field of certification.
14. We lead NB2265 employees to follow the content of the Code of Ethics and to constantly improve their professional qualifications.
15. We will inform the authority responsible for notified bodies of any changes in our quality management system or other changes related to the ability to perform MD / IVD MD conformity assessment.
16. We have full responsibility for formulating the concept of MD / IVD MD conformity assessment activities and for supervising its application as well as supervising financial matters.
17. We are personally responsible for providing the necessary resources for the continuous application of the Quality Policy and for meeting the designation and notification criteria in accordance with legislation and technical standards.

In Bratislava, 30th June, 2020

electr. signature

Katarína Tomín Srdošová, PhD.

Director of NB2265

electr. signature

Miriám Srdošová, Dipl. Ing.

Economic and personnel
Director

electr. signature

Ľubor Lysák, Dipl. Mgr.

Deputy Director of NB2265