



POL03A NR Complaints Resolving Policy

1. Each client of 3EC International a.s. (hereinafter referred to as "NB2265") or any organization or individual may complain against MD / IVD MD conformity assessment procedures or activities or against the client certified by the NB2265. A complaint shall be submitted in written form by registered post, while the complainant must indicate their identification data, subject of the complaint and necessary objective evidence for complainant's claim. The NB2265 will confirm reception of the complaint to the complainant in electronic form by e-mail. The NB2265 does not accept electronic form of the complaint, such a form is not recorded in NB2265 complaints register, unless the complainant's and NB2265 have agreed by written form differently. The NB2265 provides to the complainant information about the complaint resolution if required from the side of complainant.
2. The Director of NB2265 after the reception of a complaint considers whether the complaint relates to the MD / IVD MD conformity assessment activities of the NB2265, for which the NB2265 is responsible. If so, then this fact is confirmed to complainant, otherwise the complainant is informed that NB2265 is not responsible for MD / IVD MD conformity assessment activities included in the complaint. In case the complaint is related to activities for which is NB2265 responsible, then the Director of NB2265 designates the personnel with overall responsibility for final reviews and decision-making on certification (FR&DM) or the Quality Manager / Deputy Quality Manager (hereinafter referred to as "the Responsible person") to perform an investigation of the complaint. The investigation of the complaint cannot be investigated by such a responsible person who was previously engaged in the subject of a complaint. NB2265 hereby proclaims that acceptance, review and decision on a complaint shall not in any way be discriminatory against the complaining party.
3. The deadline for complaint resolution is 30 days from the date of its reception. In justified cases the Director of NB2265 may extend this period to 60 days.
4. If the complaint is related to a client certified by NB2265, then its resolution takes into consideration the effectivity of certified QMS-MD. Responsible person designated for resolution of this complaint informs the concerned certified client about the received complaint and requests the client for the statement within the period of set deadline.
5. In case the concerned certified client does not react on the complaint within the set time period and/or does not provide a resolution of the complaint, the NB2265 is authorized to perform an extraordinary or unannounced audit (with the aim to review the procedure of complaint's resolution of the certified client who is a subject of the complaint) at the place of the concerned client at the client's expense. Another option of the NB2265 is to review the procedure of the complaint's resolution of the certified client during the next surveillance MD / IVD MD audit (if planned within the deadline for the complaint resolution).
6. If, on the basis of gained information, records, evidence or if the client does not accept required action for the complaint's resolution in the set deadline, the NB2265 decides that the complaint is justified, the NB2265 may decide on suspension of certification, on reduction of scope of the certification or on its withdrawal.
7. The Decision on the complaint will not be issued, reviewed or approved by person who was involved in MD / IVD MD conformity assessment activities concerning the subject of a complaint. In case that the complaint is filed by the client of the NB2265, the Decision on the complaint will not be issued, reviewed nor approved by person who in the last 3 years, since the day of complaint reception, provided consultations for the client (complainant) or by a person who was an employee of the client (complainant) in the last 3 years since the day of complaint reception. In the case, the all FR&DMs / Quality Manager / Deputy Quality Manager were engaged in the subject of a complaint or based on the decision of Director of NO2265, the decision on appeal is reviewed and approved according to point 2 by the MD/ IVD MD Conformity Assessment Board (CAB) and formally prepared by Quality Manager and approved by the Director of NB2265. The NB2265



POL03A NR Complaints Resolving Policy

informs the complainant about the result and the completion of the process of complaint resolving in written form by registered post. In case of justified complaint, NB2265 provides the realization of appropriate corrective action.

8. The whole process of complaint resolving is confidential. NB2265 decides together with the client and complainant whether the subject and the resolution of the complaint is published and if so, to what extent.

9. In general, the complaint must be brought in the first instance to the NB2265. In case the complaint will not be accepted by the NB2265 in the first instance, the client has the right to contact an authority responsible for notified bodies (ÚNMS SR) in written form by registered post. At the same time, the complainant is obliged to send a copy of such a complaint to NB2265.

10. NB2265 constantly monitors and records received complaints and activities carried out for their resolution.

Elaborated by: Mark Tomin / Zuzana Maslíková

Approved by: Katarína Tomin Srdošová