



POL04A NR Appeal Resolving Policy

1. Each client of 3EC International a.s. (hereinafter referred to as "NB2265") may bring an appeal against the NB2265 decision taken in MD / IVD MD conformity assessment process. The decision taken in MD / IVD MD conformity assessment process by NB2265 in this context is referred to:

- decision on certificate suspension,
- decision on certificate withdrawal,
- decision on restriction of scope of certificate,
- decision on cancellation of application registration,
- decision on certificate refusal (hereinafter referred to as "the Decision").

2. An appeal against the Decision of NB2265 must be delivered by the client (appellant) to NB2265 at the latest 15 calendar days after the appellant receives the Decision which is the subject of an appeal. The appeal does not have a suspensive effect on the decision of NB2265 towards which the client (appellant) brings an appeal. The appeal with a justification must be submitted by client (appellant) in written form by registered post and must provide necessary objective evidence for its claim. The client (appellant) has the opportunity to formally present his/her case to NB2265. NB2265 will confirm the reception of the appeal to the client (appellant) in electronic form by e-mail.

3. Acceptance, review and decision on the appeal by NB2265 does not result in any discriminatory actions against the appellant.

4. The Director of NB2265 considers whether the appeal relates to MD / IVD MD conformity assessment activities of the NB2265 for which NB2265 is responsible. If so, then this fact is confirmed to client (appellant), otherwise the client (appellant) is informed that NB2265 is not responsible for MD / IVD MD conformity assessment activities included in the appeal.

5. In case the appeal is related to MD / IVD MD conformity assessment activities for which NB2265 is responsible, then the Director of NB2265 designates personnel with overall responsibility for final reviews and decision-making on certification (FR&DM) / Quality Manager / Deputy Quality Manager (hereinafter referred to as "the Responsible person") to perform an investigation of the appeal. Responsible person is an independent person, who was not involved in MD / IVD MD conformity assessment activities that are the subject of the appeal (was not involved in the process of decision making / decision issuance). Responsible person will investigate all documents related to the whole process, evaluate the information, in order to objectify all evidence related to the Decision. The Responsible person shall take into account previous NB2265 Decisions about appeals in objectively similar cases.

6. Following paragraph 5., NB2265 will decide on confirmation of the Decision of NB2265, which is a subject to appeal or NB2265 will decide on the need to take follow-up steps, correction or corrective actions by NB2265, needed for appeal resolving. The Decision on the appeal cannot be reviewed by person who was involved in MD / IVD MD conformity assessment activities concerning the subject of an appeal, or by a person who in the last 3 years, since the day of appeal reception provided consultations for the client (appellant) or by a person who was an employee of the client (appellant) in the last 3 years since the day of appeal reception. In the case, the all FR&DMs / Quality Manager / Deputy Quality Manager were involved in the MD / IVD MD conformity assessment activities or based on the decision of Director of NO2265, the decision on appeal is reviewed and approved according to point 5 by the MD/ IVD MD Conformity Assessment Board (CAB) and formally prepared by Quality Manager and approved by the Director of NB2265.

7. NB2265 will notice the result to the client (appellant) in written form by registered post no later than 30 days from the reception of the appeal. In justified cases the Director of NB2265 may extent this period to 60 days. By this written notice NB2265 provides official report and outcome of the appeal resolution to the appellant.



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8. In general, the appeal must be brought in the first instance to the NB2265. In case the appeal will not be accepted by NB2265 in the first instance, the client has the right to contact an appropriate authority responsible for notified bodies (ÚNMS SR) in written form by registered post. At the same time, the appellant is obliged to send a copy of such an appeal to NB2265.
9. The client has no right to appeal in the case of NB2265 unannounced audits and findings of serious violation of the rules related to the MD / IVD MD conformity assessment process and related decision of the personnel with overall responsibility for final reviews and decision-making on certification (FR&DM) on the withdrawal of the certificate within unannounced audit or unauthorized use of CE marking with the NB2265 number i.e. CE2265.
10. In case there arise any costs in connection with the NB2265 decision confirmation from the side of Authority responsible for notified bodies (ÚNMS SR), the client is obliged to settle these costs to NB2265 in its full amount.
11. NB2265 constantly monitors and records received appeals and activities carried out for their resolution.

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