

## Rejection from NB 0373

**From:** 5.1.2e  
**Date:** 2021-03-11 15:05  
**To:** 5.1.2e pdymind.com  
**CC:** 5.1.2e  
**Subject:** R: certification application

Dear 5.1.2e

at this moment the N.B.0373 is busy, and cannot take on charge new IVD certification procedures for at least two months. Please, re-contact us after two months to check newly our availability.

Below you can find some links that may be useful for you:

European Commission MEDICAL DEVICES:

[https://ec.europa.eu/growth/sectors/medical-devices\\_it](https://ec.europa.eu/growth/sectors/medical-devices_it)

Directive 98/79 / EC:

For the CE IVD reference normative documentation and the list of applicable harmonized standards see:

[https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices\\_en](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en)

For the guidelines recommended by the commission, see:

[https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance\\_it](https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_it)

recommended guideline for technical file:

<http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf>

Other EC links about SARS-CoV-2:

[https://ec.europa.eu/health/sites/health/files/md\\_sector/docs/covid-19\\_ivd-qa\\_en.pdf](https://ec.europa.eu/health/sites/health/files/md_sector/docs/covid-19_ivd-qa_en.pdf)

[https://ec.europa.eu/health/sites/health/files/preparedness\\_response/docs/covid-19\\_rat\\_common-list\\_en.pdf](https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf)

<https://covid-19-diagnostics.jrc.ec.europa.eu/>

<https://ec.europa.eu/docsroom/documents/40805>

[https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0415\(04\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0415(04))

Full list of IVD devices and 98/79/EC procedures for whom Notified Body 0373 is authorized to issue CE certification.

Products	Procedures	Articles/Annexes
<b>*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of</b>		
- *IVD 0201 - HIV infection (HIV 1 and 2)	Full quality assurance system EC type-examination Production quality assurance	Annex IV or Annex V+VII
- *IVD 0202 - HTLV I and II	Full quality assurance system EC type-examination Production quality assurance	Annex IV or Annex V+ VII
- *IVD 0203 - Hepatitis B, C and D	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV or Annex V+ VII
<b>*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</b>		
- *IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV or Annex V + VII or Annex V+ VI
- *IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV or Annex V + VII or Annex V+ VI
- *IVD 0307 - Tumoral marker: PSA	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV or Annex V + VII or Annex V+ VI
<b>*IVD 0400 - Devices for self-testing</b>		
- *IVD 0401 - Clinical chemistry	EC declaration of conformity	Annex III.6
- *IVD 0402 - Haematology	EC declaration of conformity	Annex III.6
- *IVD 0403 - Immunology	EC declaration of conformity	Annex III.6
- *IVD 0404 - Molecular biology	EC declaration of conformity	Annex III.6
- *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity	Annex III.6
- *IVD 0406 - Specimen receptacles	EC declaration of conformity	Annex III.6

Best Regards,

5.1.2e

Notified Body 0373 Istituto Superiore di Sanità

**From:** [REDACTED] 5.1.2e  
**Date:** 2021-03-10 18:56  
**To:** [REDACTED] 5.1.2e @dymind.com  
**CC:** [REDACTED] 5.1.2e @itczlin.cz  
**Subject:** RE: certification application\_refusal

Rejection from NB1023

Dear [REDACTED] 5.1.2e

Thank you for contacting ITC and trust in our services.

Unfortunately we are forced to inform you that we cannot provide conformity assessment of this type of products.

We are sorry we have not better information for you.

Thks for your understanding.

Best Regards,

[REDACTED] 5.1.2e



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**From:** Tomáš Závisek [REDACTED] 5.1.2e @itczlin.cz  
**Sent:** Wednesday, March 10, 2021 11:35 AM  
**To:** Markéta Klinkovská  
**Subject:** FW: certification application