EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
SANTE.DDG1.B.6/MP/mp(2021)2764076

Subject: Your application for access to documents – Ref GestDem No 2021/2082

Dear Mr Holmstedt,

We refer to your application of 06 April 2021 in which you make a request for access to documents, registered on the same date under the above-mentioned reference number.

1. Scope of your request

You request, on the basis of Regulation (EC) No 1049/2001[1], access to:

documents on all RT-PCR / RT-qPCR / PCR tests for detection of SARS-CoV-2 that have undergone a conformity assessment and qualified for the CE (Conformité Européenne) mark

2. No documents held

We regret to inform you that the Commission does not hold any documents that would correspond to the description given in your application.

We consider your request to cover the technical documentation of these tests to demonstrate conformity with the currently applicable legislation for these tests (Directive 98/79/EC). According to the Directive, conformity assessment for such tests for professional use is performed by the manufacturer, who then completes the EU declaration of conformity and affixes the CE-marking to the product. For tests intended for lay users, an additional step is verification of design aspects of the device by a notified body, which issues the corresponding certificate. Further information on the conformity assessment process is available on the medical device guidance page of the European Commission, and in particular in the guidance document COVID-19 TESTS: Q&A on in vitro diagnostic medical device conformity assessment and performance in the context of COVID-19. The

[1] Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

By registered letter with acknowledgment of receipt[1]
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Commission is not involved in conformity assessment and neither receives nor is in the possession of the technical documentation held by the manufacturers or notified bodies.

As specified in Article 2(3) of Regulation (EC) No 1049/2001, the right of access as defined in that regulation applies only to existing documents in the possession of the institution.

Given that no such documents, corresponding to the description given in your application, are held by the Commission, the Commission is not in a position to fulfil your request.

3. Means of redress

In accordance with Article 7(2) of Regulation (EC) No 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretariat-General of the Commission at the following address:

European Commission
Secretariat-General
Transparency, Document Management & Access to Documents (SG.C.1)
BERL 7/076
B-1049 Brussels

or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,

Sandra Gallina
Director-General