NOTIFICATION

Addendum

The following communication, dated 7 May 2024, is being circulated at the request of the delegation of the United States of America.

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**Title:** Medical Devices; Laboratory Developed Tests

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| **Reason for Addendum:** |
| [ ] | Comment period changed - date:  |
| [ ] | Notified measure adopted - date:  |
| [X] | Notified measure published - date: 6 May 2024 |
| [X] | Notified measure enters into force - date: 5 July 2024 |
| [X] | Text of final measure available from[[1]](#footnote-1): 89 Federal Register (FR) 37286, Title 21 Code of Federal Regulations (CFR) Part 809:<https://www.govinfo.gov/content/pkg/FR-2024-05-06/html/2024-08935.htm><https://www.govinfo.gov/content/pkg/FR-2024-05-06/pdf/2024-08935.pdf><https://members.wto.org/crnattachments/2024/TBT/USA/final_measure/24_03122_00_e.pdf> |
| [ ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [ ] | Content or scope of notified measure changed and text available from1: New deadline for comments (if applicable):  |
| [ ] | Interpretive guidance issued and text available from1:  |
| [ ] | Other:  |

**Description:** The Food and Drug Administration is issuing a final rule to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act ([FD&C Act](https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act)) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, the Food and Drug Administration is phasing out its general enforcement discretion approach for laboratory developed tests (LDTs) so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs and LDTs for unmet needs. This phaseout policy is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance.

This rule is effective 5 July 2024.

[Title 21 Code of Federal Regulations (CFR) Part 809](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-809)

This final rule and the proposed rule notified as [G/TBT/N/USA/2054](https://eping.wto.org/en/Search?domainIds=1&documentSymbol=usa%2F2054&viewData=G%2FTBT%2FN%2FUSA%2F2054) are identified by Docket Number FDA-2023-N-2177. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2023-N-2177/document> and provides access to primary documents as well as comments received. Documents are also accessible from [Regulations.gov](http://www.regulations.gov/) by searching the Docket Number.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)