WORLD TRADE ORGANIZATION

G/TBT/N/USA/1839/Add.2

8 December 2025

(25-8220)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 5 December 2025, is being circulated at the request of the delegation of the United States of America.

Title: Medical Devices; Quality Management System Regulation Technical Amendments

Reason for Addendum:	
[ ]	Comment period changed - date:
[ ]	Notified measure adopted - date:
[ ]	Notified measure published - date:
[X]	Notified measure enters into force - date: 2 February 2026
[ ]	Text of final measure available from[1]:
[ ]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
[ ]	Content or scope of notified measure changed and text available from[1]: New deadline for comments (if applicable):
[ ]	Interpretive guidance issued and text available from[1]:
[X]	Other: Final rule; technical amendments https://members.wto.org/crnattachments/2025/TBT/USA/25_08733_00_e.pdf

Description: The Food and Drug Administration (FDA, the Agency, or we) is amending certain medical device regulations to revise references and language in existing Code of Federal Regulations (CFR) provisions to conform with the final rule "Medical Devices; Quality System Regulation Amendments" (QMSR Final Rule) (notified as G/TBT/N/USA/1839/Add.1). This rule does not impose any new requirements on affected parties. This action is editorial in nature to correct errors, conform regulatory references, and ensure accuracy and clarity in the Agency's regulations.

This rule is effective 2 February 2026.

90 Federal Register (FR) 55978, 4 December 2025; Title 21 Code of Federal Regulations (CFR) Parts 801, 803, 812, 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892:

https://www.govinfo.gov/content/pkg/FR-2025-12-04/html/2025-21955.htm

[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.

https://www.govinfo.gov/content/pkg/FR-2025-12-04/pdf/2025-21955.pdf

This final rule; technical amendments is identified by Docket Number FDA-2025-N-4635. The Docket Folder is available from Regulations.gov at https://www.regulations.gov/docket/FDA-2025-N-4635/document and provides access to primary documents. Documents are also accessible from Regulations.gov by searching the Docket Number.

Previous actions notified under the symbol G/TBT/N/USA/1839 are identified by Docket Number FDA-2021-N-0507. The Docket Folder is available from Regulations.gov at https://www.regulations.gov/docket/FDA-2021-N-0507/document and provides access to primary and supporting documents as well as comments received. Documents are also accessible from Regulations.gov by searching the Docket Number.