NOTIFICATION

Addendum

The following communication, dated 23 November 2021, is being circulated at the request of the delegation of the United States of America.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title:** Microbiology Devices; Reclassification of Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Assay Devices, To Be Renamed Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Tests

|  |
| --- |
| **Reason for Addendum:** |
| [  ] | Comment period changed - date:  |
| [  ] | Notified measure adopted - date:  |
| [X] | Notified measure published - date: 22 November 2021 |
| [X] | Notified measure enters into force - date: 22 December 2021 |
| [X] | Text of final measure available from[[1]](#footnote-1): <https://www.govinfo.gov/content/pkg/FR-2021-11-22/html/2021-25379.htm><https://www.govinfo.gov/content/pkg/FR-2021-11-22/pdf/2021-25379.pdf><https://members.wto.org/crnattachments/2021/TBT/USA/final_measure/21_7290_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| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |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:**

TITLE: Microbiology Devices; Reclassification of Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Assay Devices, Renamed to Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify nucleic acid-based hepatitis C virus (HCV) ribonucleic acid (RNA) devices intended for the qualitative or quantitative detection or genotyping of HCV RNA, postamendments class III devices (product codes MZP and OBF), into class II (general controls and special controls), subject to premarket notification. FDA is renaming and codifying these devices under the classification regulation named "nucleic acid-based hepatitis C virus (HCV) ribonucleic acid tests." FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of these devices.

DATES: This order is effective 22 December 2021.

This Final amendment; final order and the Proposed amendment; proposed order; request for comments notified in [G/TBT/N/USA/1607](https://docs.wto.org/imrd/directdoc.asp?DDFDocuments/t/G/TBTN20/USA1607.DOCX) are identified by Docket No. FDA–2020–N–1088.  The docket folder is available on [Regulations.gov](https://www.regulations.gov/) and provides access to primary and supporting documents as well as comment received at <https://www.regulations.gov/docket/FDA-2020-N-1088>.  Documents are also accessible from [Regulations.gov](https://www.regulations.gov/) by searching the Docket Number.

**\_\_\_\_\_\_\_\_\_\_**

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)