NOTIFICATION

Addendum

The following communication, dated 27 April 2022, is being circulated at the request of the delegation of Costa Rica.

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**Title**: *RTCR 405:2007 Reglamento para Registro, Clasificación, Importación, y Control de Equipo y Material Biomédico* (Costa Rican Technical Regulation (RTCR) No. 405:2007 "Regulations for the Registration, Classification, Importation and Inspection of Biomedical Equipment and Material") (19 pages, in Spanish)

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| **Reason for Addendum:** |
| [ ] | Comment period changed - date: |
| [ ] | Notified measure adopted - date: |
| [ ] | Notified measure published - date: |
| [ ] | Notified measure enters into force - date: |
| [X] | Text of final measure available from[[1]](#footnote-1):http://reglatec.go.cr/reglatec/principal.jsp |
| [ ] | Notified measure withdrawn or revoked - date:Relevant symbol if measure re-notified: |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: |
| [X] | Other:Comprehensive review of RTCR No. 405:2007 "Regulations for the Registration, Classification, Importation and Inspection of Biomedical Equipment and Material"Description: In accordance with good regulatory practices, RTCR No. 405:2007 "Regulations for the Registration, Classification, Importation and Inspection of Biomedical Equipment and Material" has been reviewed and a decision made to publish a new technical regulation.TITLE: *RTCR 505: 2022 Equipo y Material Biomedico. Clasificación, Registro, Importación, Etiquetado, Publicidad, Vigilancia y Control* (RTCR No. 505:2022 "Biomedical Equipment and Material. Classification, Registration, Importation, Labelling, Advertising, Monitoring and Inspection") (56 pages, in Spanish)AGENCY: *Ministerio de Salud* (Ministry of Health)MEASURE: Technical regulation<https://members.wto.org/crnattachments/2022/TBT/CRI/22_3088_00_s.pdf> |

**Description**: **SUMMARY:** The purpose of this technical regulation is to establish the requirements and processes necessary for the classification, registration, importation and inspection of biomedical equipment and material intended for human use. It applies to biomedical equipment and material and their accessories, as well as to mobile device software and applications (apps) for medical use, that are produced, imported or marketed in Costa Rican territory.

**DATES:** The final date for comments is 30 days from the date of notification.

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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 measure/change to the measure/interpretative guidance can be obtained. [↑](#footnote-ref-1)