



### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

<b>1. Notifying Member:</b> <u>Brazil</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Brazilian Health Regulatory Agency (ANVISA) <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>  National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b>  HS Code(s): medical devices (2936, 2937, 3001, 3002, 3003, 3004, 3006)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Normative Instruction number 878, 23 July 2020. <b>Language(s):</b> Portuguese. <b>Number of pages:</b> 4.
<b>6. Description of content:</b> This draft normative instruction establishes technical requirements for medical devices selected to economic monitoring by Anvisa.  Draft: <a href="http://portal.anvisa.gov.br/documents/10181/4247877/CONSULTA+P%C3%9ABLICA+N+878+GECOR.pdf/ebe1bc43-f979-4d81-accb-b4d817a2b031">http://portal.anvisa.gov.br/documents/10181/4247877/CONSULTA+P%C3%9ABLICA+N+878+GECOR.pdf/ebe1bc43-f979-4d81-accb-b4d817a2b031</a>  Comment form: <a href="http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=58342">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=58342</a>
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health.
<b>8. Relevant documents:</b> : 1) Brazilian Official Gazette 144 on 29 July 2020, section 1, page 71 2) RIA report  <a href="https://www.in.gov.br/web/dou/-/consulta-publica-n-878-de-23-de-julho-de-2020-269154956">https://www.in.gov.br/web/dou/-/consulta-publica-n-878-de-23-de-julho-de-2020-269154956</a>  <a href="http://portal.anvisa.gov.br/documents/10181/4247877/Relat%C3%B3rio+de+AIR+sobre+Monitoramento+Econ%C3%B4mico+de+Produtos+para+Sa%C3%BAde+no+Brasil.pdf/2f9b1ce3-ae07-46c2-a2d6-503ccdf4c4eb">http://portal.anvisa.gov.br/documents/10181/4247877/Relat%C3%B3rio+de+AIR+sobre+Monitoramento+Econ%C3%B4mico+de+Produtos+para+Sa%C3%BAde+no+Brasil.pdf/2f9b1ce3-ae07-46c2-a2d6-503ccdf4c4eb</a>
<b>9. Proposed date of adoption:</b> To be determined after the end of the consultation period.  <b>Proposed date of entry into force:</b> To be determined after the end of the consultation period.

**10. Final date for comments:** 5 October 2020

**11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

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