



### NOTIFICATION

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

<b>1. Notifying Member: <u>BRAZIL</u></b> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas  <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>  <i>Assessoria de Assuntos Internacionais - AINTE</i> International Affairs Office <i>Agência Nacional de Vigilância Sanitária - Anvisa</i> Brazilian Health Regulatory Agency Tel: +(55 61) 3462 5402/5404/5406 E-mail: <a href="mailto:rel@anvisa.gov.br">rel@anvisa.gov.br</a> Web-site: <a href="http://portal.anvisa.gov.br/english">http://portal.anvisa.gov.br/english</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>  Biological Products
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Resolution 633, 27 March 2019, published by Brazilian Official Gazette Nº 61 Section 1 page 99 (1 page(s), in Portuguese)  Draft:  <a href="http://portal.anvisa.gov.br/documents/10181/3430631/CP+633-2019.pdf/c61cfbb5-5c2a-4bbd-8e22-97d1c9d06763">http://portal.anvisa.gov.br/documents/10181/3430631/CP+633-2019.pdf/c61cfbb5-5c2a-4bbd-8e22-97d1c9d06763</a>  Comment form:  <a href="http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=46336">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=46336</a>
<b>6. Description of content:</b> This draft resolution establishes the minimal requirements for marketing authorization (registration) of biological products of lower complexity.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety; Protection of Human Health

<b>8. Relevant documents:</b>
<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.
<b>10. Final date for comments:</b> 30/06/2019
<b>11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b> Assessoria de Assuntos Internacionais - AINTE International Affairs Office Agência Nacional de Vigilância Sanitária - Anvisa Brazilian Health Regulatory Agency Tel: +(55 61) 3462 5402/5404/5406 E-mail: <a href="mailto:rel@anvisa.gov.br">rel@anvisa.gov.br</a>