



Committee on Technical Barriers to Trade

NOTIFICATION

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

1. Notifying Member: BRAZIL If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: Brazilian Health Surveillance Agency - Anvisa Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: 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 The comments to this Draft Regulation shall be sent to http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=21796
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): implantable products which are used in procedures of permanent artificial pigmentation on skin.
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution nº 61, August 17 th 2015, regarding the changing of safety and efficacy requirements to registering implantable products which are used in procedures of permanent artificial pigmentation on skin (3 pages, Portuguese).
6. Description of content: Draft Technical Resolution nº 61, August 17 th 2015, regarding the changing of safety and efficacy requirements to registering implantable products which are used in procedures of permanent artificial pigmentation on skin. This Draft Technical Resolution modifies the item 5.2 of Part 5 of the Annex of Resolution RDC 55/2008.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8. Relevant documents: 1) Brazilian Official Journal (Diário Oficial da União), August 18 th 2015; Section 1, p. 33; 2) RDC 55/2008; 3) Brazilian Official Journal; 4) Not Stated.

9.	Proposed date of adoption:	To be determined after the end of the consultation period.
	Proposed date of entry into force:	On the date of the publication.
10.	Final date for comments: October 23 th , 2015.	
11.	Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: Agency Responsible Brazilian Health Surveillance Agency - Anvisa SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/wps/wcm/connect/2d98aa80498640d4bd7ebfda875a0177/CP+61-2015+-+Minuta.pdf?MOD=AJPERES	