



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>BRAZIL</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Brazilian Health Regulatory Agency (Anvisa) 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: National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2918 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=33294
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): medical devices
5. Title, number of pages and language(s) of the notified document: Draft Resolution N° 546, 3 September 2018 (12 page(s), in Portuguese)
6. Description of content: This Draft Resolution 546/2018 lays down technical requirements for the manufacturing, marketing, import, export and exposure to use of custom-made and patient specific medical devices and medical devices exempt from registration. This Draft Resolution does not apply to active medical device, in vitro diagnostic medical devices, medical devices under clinical investigation and services provided by dental prosthesis laboratories. The requirements established in this Resolution address, among others: good manufacturing practices, labelling, traceability labels, technovigilance, product dossier, safety and efficacy requirements. The adaptable medical device is regulated by Anvisa and must comply to the requirements established in the Collegiate Board Resolution - RDC n° 185, from 22 October 2001, Collegiate Board Resolution - RDC n° 40, from 26 August 2015 and other current specific regulations. Custom-made and patient specific medical devices national manufacturing and import companies must keep documents to ensure traceability to the patient. Anvisa will not provide previous authorization for product manufacturing for custom-made

<p>and patient specific medical devices.</p> <p>The Draft Resolution 546, 3 September 2018 is available at</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety</p>
<p>8. Relevant documents: Collegiate Board Resolution - RDC nº 56, from 06 April 2001; Collegiate Board Resolution - RDC nº 185, from 22 October 2001; Collegiate Board Resolution - RDC nº 67, from 21 December 2009; Collegiate Board Resolution - RDC nº 16, from 28 March 2013; Collegiate Board Resolution - RDC nº 40, from 26 August 2015.</p>
<p>9. Proposed date of adoption: On the date of its publication</p> <p>Proposed date of entry into force: 90 days after the date of its publication</p>
<p>10. Final date for comments: 12 November 2018</p>
<p>11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>Agency Responsible Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: http://portal.anvisa.gov.br/english</p> <p>http://portal.anvisa.gov.br/documents/10181/3254343/CONSULTA+P%C3%9ABLICA+N%C2%BA+546+GGTPS.pdf/9cb02cdb-903d-41a2-a168-8f7f005fb8ba</p>