



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: Brazil If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: ANVISA – Brazilian Health Surveillance Agency 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 2563.2821 Telefax: +(55) 21 2502.6542 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=15139
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): Dental bleaching agents classified as medical devices.
5. Title, number of pages and language(s) of the notified document: Draft Resolution nº 14, April 1th 2014, that disposes about dental bleaching agents control. (3 pages, in Portuguese)
6. Description of content: This draft Resolution establishes criteria for packing and labelling of dental bleaching agents which are classified as medical devices. According to this draft technical regulation, the distribution of medical devices used in dental bleaching, containing hydrogen peroxide or carbamide peroxide with concentrations of these substances higher than 3%, alone or in combination, is subject to the dental prescription. Packaging and labelling of dental bleaching agents containing those substances shall include, in red stripe and emphasized, the phrase: "Sale under dental prescription". The leaflets shall include, emphasized and in a larger font, the phrase: "Sale under dental prescription."

<p>It's allowed the sale of the products directly to dental surgeons and legal persons that provide dental services.</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: (1) Brazilian Official Journal (Diário Oficial da União), April 4th 2014, Section 1, Draft Resolution (Consulta Pública) number 14, April 1th, 2014, issued by Brazilian Health Surveillance Agency – Anvisa; (2) Not Applicable; (3) Brazilian Official Journal; (4) Not Applicable.</p>
<p>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 adoption.</p>
<p>10. Final date for comments: 09 June 2014</p>
<p>11. Text 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 Regulatory Agency – ANVISA SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: 55 61 3462-5402 E-mail: rel@anvisa.gov.br Website: http://portal.anvisa.gov.br/wps/wcm/connect/9277b88043841dc1ac70ac493cc3c60f/Consulta+P%C3%BAblica+n%C2%B0+14+GGTPS.pdf?MOD=AJPERES</p>