NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Brazil  **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 2145.3817 Telefax: +(55) 21 2563.5637 Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)  Web-site: [www.inmetro.gov.br/barreirastecnicas](http://www.inmetro.gov.br/barreirastecnicas) |
| **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):** Dried glands and other organs for organo-therapeutic uses, whether or not powdered; extracts of glands or other organs or their secretions, for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, n.e.s (HS 3001); Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excl. yeasts) and similar products (HS 3002); Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS 3003); Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, in measured doses or put up for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS 3004); Pharmaceutical preparations and products of subheading Nos 3006.10.10 to 3006.60.90 (HS 3006) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Normative Instruction number 68, 1 September 2020 (2 page(s), in Portuguese) |
| **6.** | **Description of content:** This Normative Instruction establishes the inclusion of a declaration in the label of medical devices informing the existence of a new formula changing its composition. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  1) Brazilian Official Gazette 170 on 03 September 2020, section 1, page 74 2) Brazilian Official Gazette 170 on 03 September 2020, section 1, page 74 3) Resolution of the Collegiate Board - RDC No. 421 of 01 September 2020  <https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-68-de-1-de-setembro-de-2020-275656283>  <https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-421-de-1-de-setembro-de-2020-275656506>  [[http://antigo.anvisa.gov.br/legislacao#/visualizar/432064](http://antigo.anvisa.gov.br/legislacao" \l "/visualizar/432064)](http://antigo.anvisa.gov.br/legislacao#/visualizar/432064) |
| **9.** | **Proposed date of adoption:** 1 September 2021  **Proposed date of entry into force:** 1 September 2021 |
| **10.** | **Final date for comments:** Not applied |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Brazilian Health Regulatory 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://www.anvisa.gov.br)  <https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-68-de-1-de-setembro-de-2020-275656283> |