



IMDRF International Medical
Device Regulators Forum

REGULATORY UPDATE

**IMDRF Stakeholders Meeting
Tokyo, Japan, March 2015**

**ANVISA
Brazil**



REGULATORY UPDATE

➤ **ANVISA Normative Instruction n°11/2014**

- Update of technical standards (ISO) regarding mandatory certification of electromedical equipments.
- Aim: to improve marketing control with impact in reduction of the risks to the user / patient.



➤ **Law n°13.097/2015 (19/1/2015)**

- Use of confidential information of audits received under the scope of agreements with foreign authorities for GMP certification
- Authorizes inspections and audits by national or international organizations recognized by ANVISA
- Exclude revalidation for the Operating Company Authorization for importers and companies installed in Brazil
- Allows the marketing authorization of products to be valid up to 10 years (current situation: marketing authorization valid for 5 years) - to be regulated



➤ **RDC ANVISA nº 6/2015**

- Packaging, labeling and marketing of whitening teeth products classified as medical devices
- Teeth whitening with composition higher than 3% of hydrogen peroxide shall be marketed only under professional prescription (dentist)



➤ **Clinical Trials**

- Defines requirements to approve Clinical Trials with medical devices.
- Publication at the National Gazette (DOU) .



TASK FORCE

➤ **Medical Devices Reprocessing** **(Ordinance ANVISA nº 1.910/2014)**

- To evaluate the current situation of products and services related to medical devices reprocessing
- To propose directives for the review of RDC 156/2006 (requirements for marketing authorization, labelling and reprocessing of MD), R.E. 2.605/2006 and R.E. 2.606/2006 (list of single use MD unsuitable for reprocessing).



TASK FORCE

- **Medical Devices Working Group
(Interministries Ordinance n° 38/2015
Ministries of Health, Finance and Justice)**
 - Restructuring and improvement of transparency of production, import, purchase, distribution, use, taxation, technology assessment and incorporation and price regulation procedures
 - Improvement of clinical regulation and access to medical devices (prosthesis, orthosis, special materials)



RISK COMMUNICATION

- **Meeting with Glucose meter Importers (September 2014)**
 - Present a study developed by INMETRO and Federal University of Viçosa – UFV on evaluation of Glucose meter's instructions for use .
 - Conduct Adjustment Agreement signed to solve the problems detected and improve control (focus on accuracy)



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Thank you

[Conclusion]