REGULATORY UPDATES

IMDRF Stakeholders Meeting
Brasília, Brazil, March 2016

ANVISA
Brazil
ANVISA Normative Instruction nº 04 (24/09/2015)

- Update of technical standards (ISO/IEC) regarding mandatory certification of electromedical equipments.
- Aim: to improve marketing control, intending reduction of risks to user / patient.
RDC ANVISA nº 52 (27/11/2015)

- Sets registration requirements for HIV self-testing products with screening purposes.
Regulatory Updates

Law

Law nº13.202 (09/12/2015)

- Updates fees for regulatory activities.
Regulatory Updates

Resolution

Resolution RE n. 3454, published on December 16th 2015
✓ Allows ANVISA to use MDSAP regulatory audit outcomes from BSI Group America Inc. to issue the Anvisa’s GMP certificate.

Resolution RE n. 80, published on January 11th 2016
✓ Allows ANVISA to use MDSAP regulatory audit outcomes from TUV SUD America Inc. to issue the Anvisa’s GMP certificate.
Portaria INMETRO nº 54 (01/02/2016) - Approves the improvement of Conformity Assessment Requirements for equipments under Health Surveillance System.
RDC ANVISA nº 64 (02/24/2016)

- Aligns biological safety requirements for tattoo inks to the ISO 10993 requirements.
THANK YOU!

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