



IMDRF

International Medical
Device Regulators Forum

REGULATORY UPDATE

IMDRF Stakeholders Meeting
Florianópolis, Brazil

September 2016

ANVISA

Brazil



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Regulatory Updates Resolution

➤ **RDC ANVISA n° 94 (27/07/2016)**

- Update of technical standards for surgical and non-surgical gloves.



Regulatory Updates Resolution

➤ **RDC ANVISA n° 95 (27/07/2016)**

- Extending for three years the deadline to develop the technical dossier for IVD products; and for two years to equipments and materials, according to IMDRF WG N9 e N13 documents (ToC).



Regulatory Updates Resolution

- **Resolution RE n. 859 published on april 7th 2016**
 - ✓ Allows ANVISA to use MDSAP regulatory audit outcomes from **Intertek Testing Services NA Inc.** to issue the GMP certificate



Regulatory Updates Resolution

- **Resolution RE n. 2.058 published on august 1st 2016**
 - ✓ Allows ANVISA to use MDSAP regulatory audit outcomes from **Laboratoire National de Métrologie et d'Essais (G-MED Certification Division)** to issue the GMP certificate



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THANK YOU!