



IMDRF

International Medical
Device Regulators Forum

Regulatory and Policy Updates ANVISA

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Regulatory Updates



- ANVISA has launched the National Implant Registry (RNI). The online system will initially collect voluntary registration information on surgical procedures for hip and knee prostheses, and coronary stents.
- In the future, the RNI will be compulsory for all health services in Brazil, and may also be expanded to include other implantable devices.



Regulatory Updates



- **Resolution RDC n° 232/2018-** Mandatory bar code (UDI standard) into patient cards of cardiovascular stents, hip and knee prostheses.



Regulatory Updates



- **Normative Instruction n° 24/2017-** Compulsory attendance to ISO 15197/2013 standard for self monitoring blood glucose devices.
 - Compliance with the standard will be compulsory in Nov /2018. All devices that do not comply with the regulation will be withdrawn from the market.



Regulatory Updates

- **Public Consultation n° 528/2018** - Simplification of the regulatory process for the lowest-risk medical devices.
- If approved, the regulatory process change for Class I devices (including IVDs) from Cadastro (simplified approval) to a simple notification.
- The 60-days comment period is closed and ANVISA is working on the comments received.



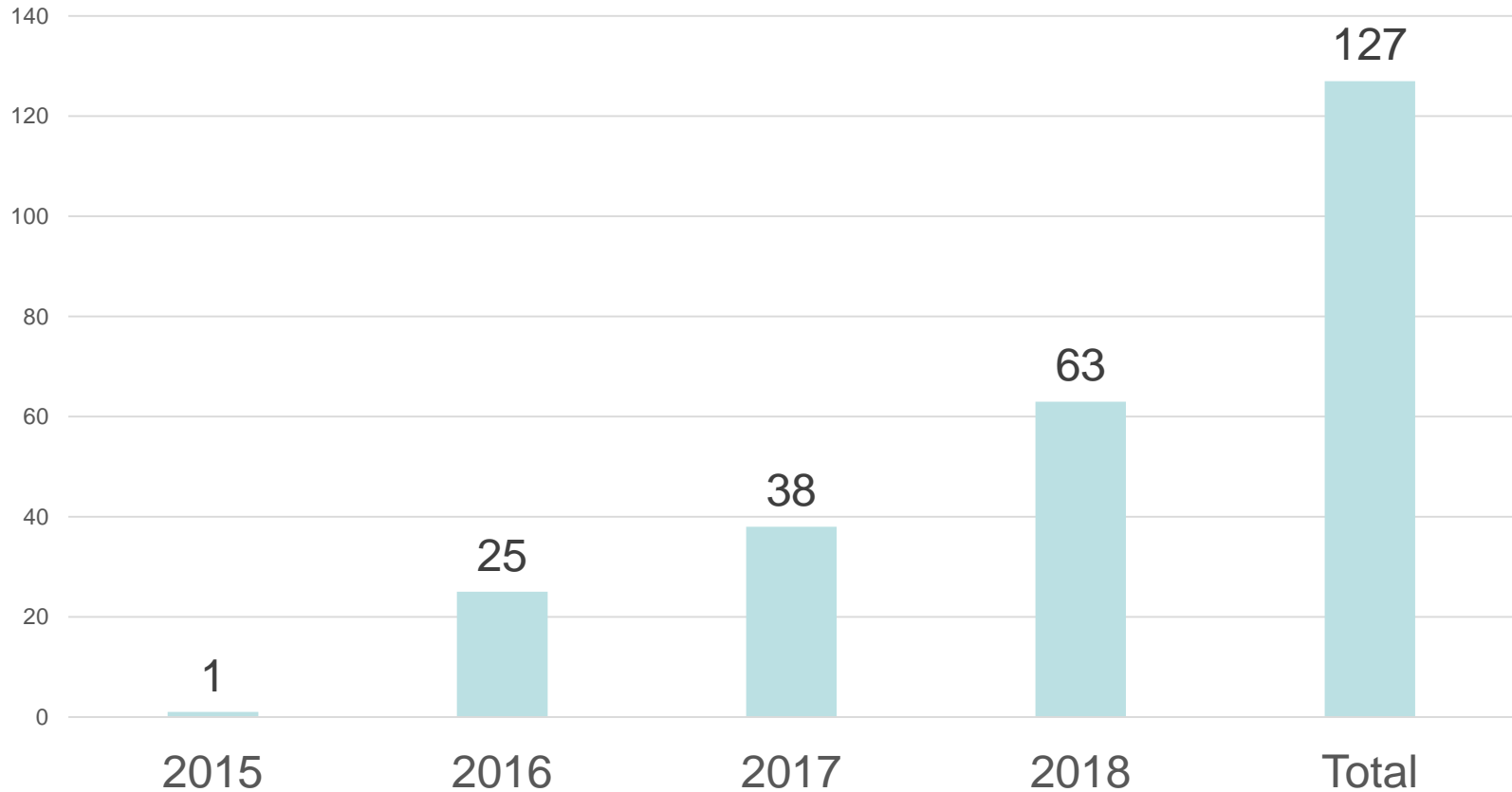
Regulatory Updates

- ✓ Auditing Organizations Recognized by ANVISA (Allows ANVISA to use MDSAP regulatory audit outcomes to issue the GMP certificate)

Auditing Organization	Resolution	Date	Published on	Expiry date
Laboratoire National de Métrologie et d'Essais (GMED Certification Division)	31	05/01/2017	09/01/2017	30/06/2018
DQS Medizinprodukte GmbH	194	24/01/2017	25/01/2017	31/12/2018
DEKRA Certification B.V.	193	24/01/2017	25/01/2017	31/12/2018
TUV SUD America Inc.	324	07/02/2017	08/02/2017	31/12/2020
Intertek Testing Services NA Inc.	323	07/02/2017	08/02/2017	31/12/2020
BSI Group America Inc.	651	13/03/2017	14/03/2017	27/02/2021
National Standards Authority of Ireland (NSAI)	1.783	06/07/2017	07/07/2017	15/06/2019
Lloyd's Register Quality Assurance Inc.	2.057	28/07/2017	31/07/2017	16/07/2019
UL Medical and Regulatory Services of UL LLC	2.226	10/08/2017	23/08/2017	03/08/2021
TUV Rheinland of North America, Inc	2.554	08/09/2017	29/09/2017	31/07/2018
QMI-SAI Canada Limited	2.553	29/09/2017	29/09/2017	31/07/2018
SGS United Kingdom Ltd.	3.432	11/12/2017	02/01/2018	11/12/2021
NSF Health Sciences Certification LLC	3.433	11/12/2017	02/01/2018	11/12/2019

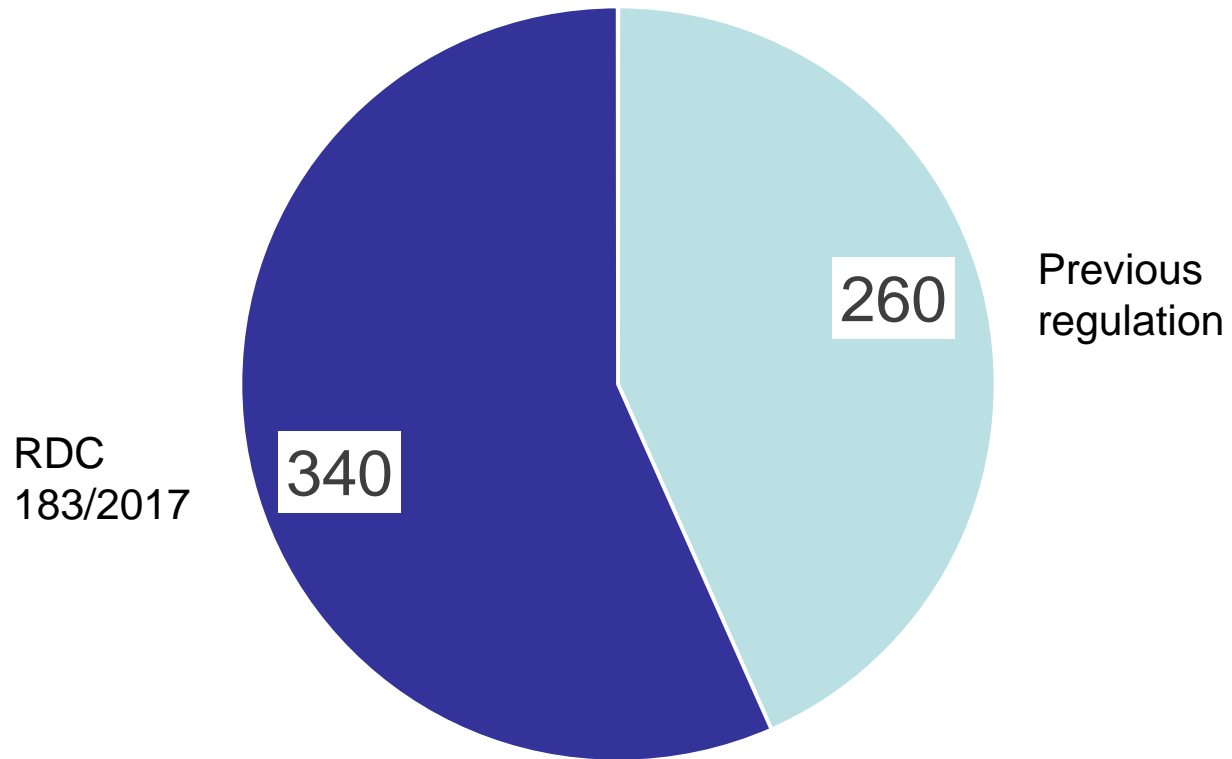


ANVISA's GMP Certification using MDSAP audit reports





GMP Certifications 2018





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Thank you!

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