Regulatory Convergence and Reliance Mechanisms for Medical Devices

Medical Device Regulatory Convergence Project (MDRC)

Good Regulatory Practices & Technical Competencies

Pharmacy and Poisons Board & Regulated Sector

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Medical Devices Office
Brazilian Health Regulatory Agency

Nairobi, 24 August 2023

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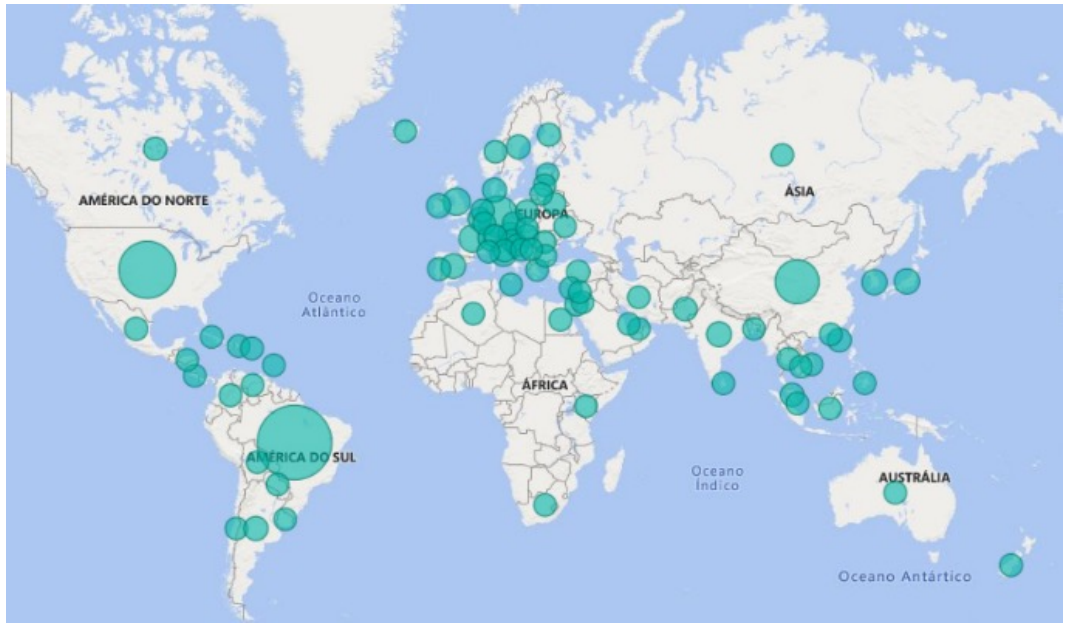
Agência Nacional de Vigilância Sanitária

Origin of Licensed MD in Brazil

Posição	País	Reg. / Notif.	%
0	Brasil	26546	30,11%
1	EUA	15613	18,40%
2	China	12462	13,99%
3	Alemanha	8484	10,02%
4	Itália	2284	2,64%
5	França	2197	2,60%
6	Reino Unido	1605	2,40%
7	Suíça	1588	1,91%
8	Coreia do Sul	1433	1,75%
9	Japão	1384	1,53%
10	Índia	1282	1,49%
11	Espanha	1030	1,16%
12	Argentina	809	0,96%
13	Irlanda	710	0,85%
14	Taiwan	706	0,79%
15	Paquistão	672	0,79%
16	Suécia	612	0,73%
17	Dinamarca	576	0,68%
18	Israel	483	0,56%
19	Turquia	478	0,55%
20	Malásia	474	0,55%



National	31,6%
Imported	68,4%
	(Mar 2023)

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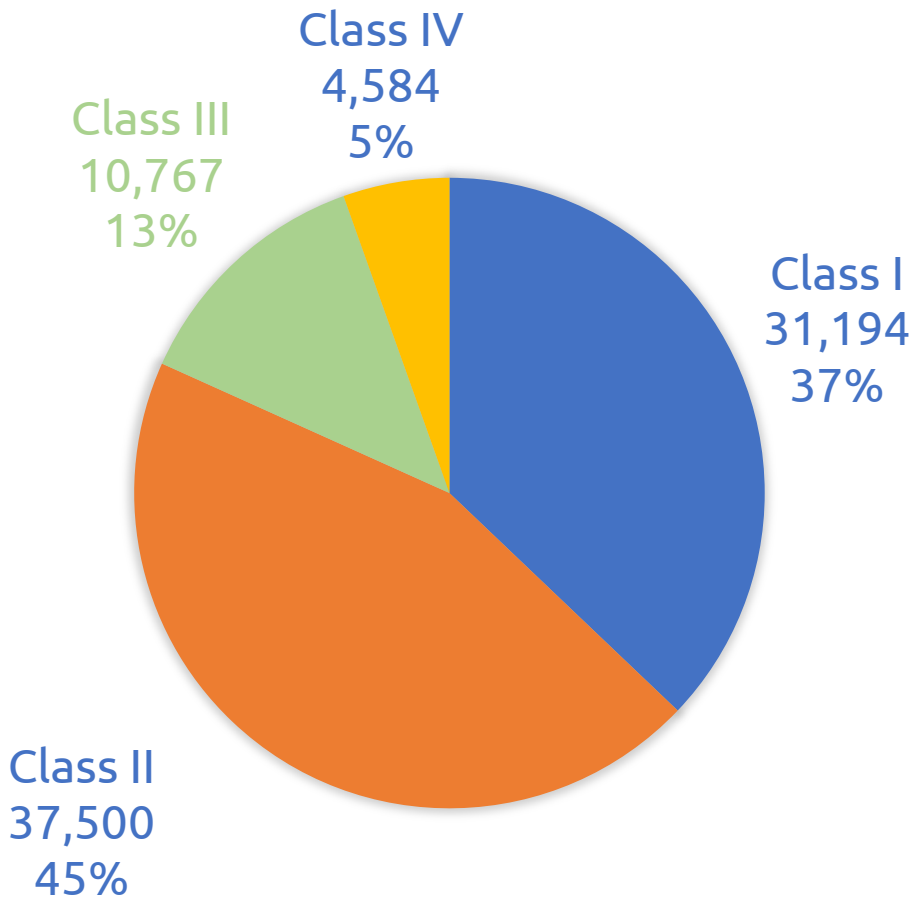
Distribution of Licensed MD by Risk Class



Total
84.045
Active licenses
of Medical Devices
(Mar 2023)

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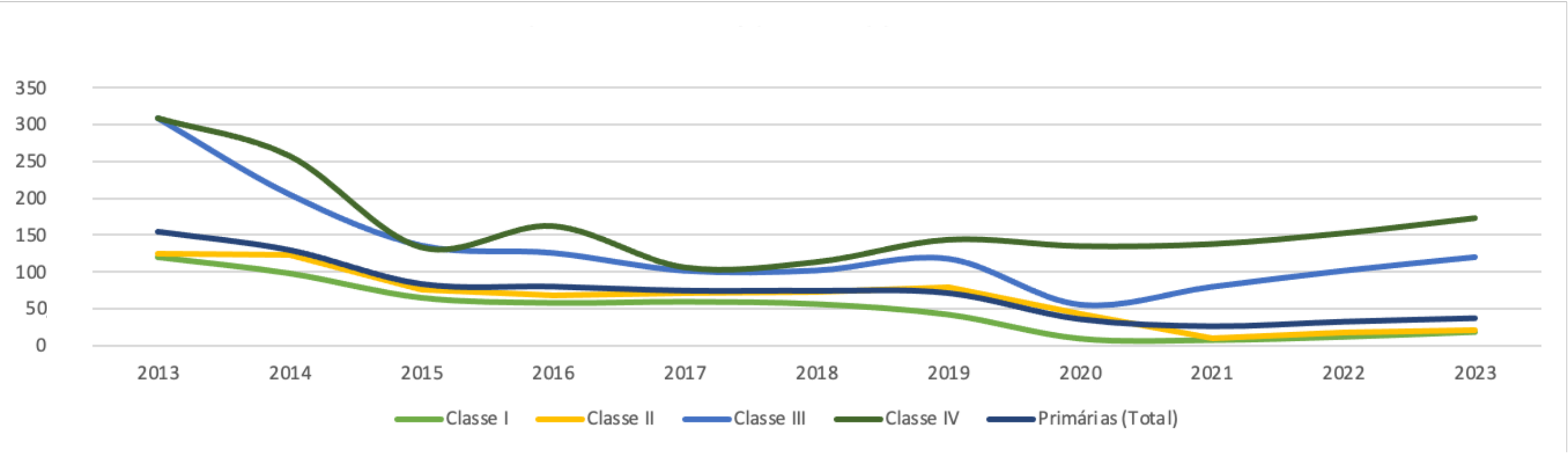
Medical Device Market Authorization



Average Time to Final Decision from ANVISA per Risk Class (days)

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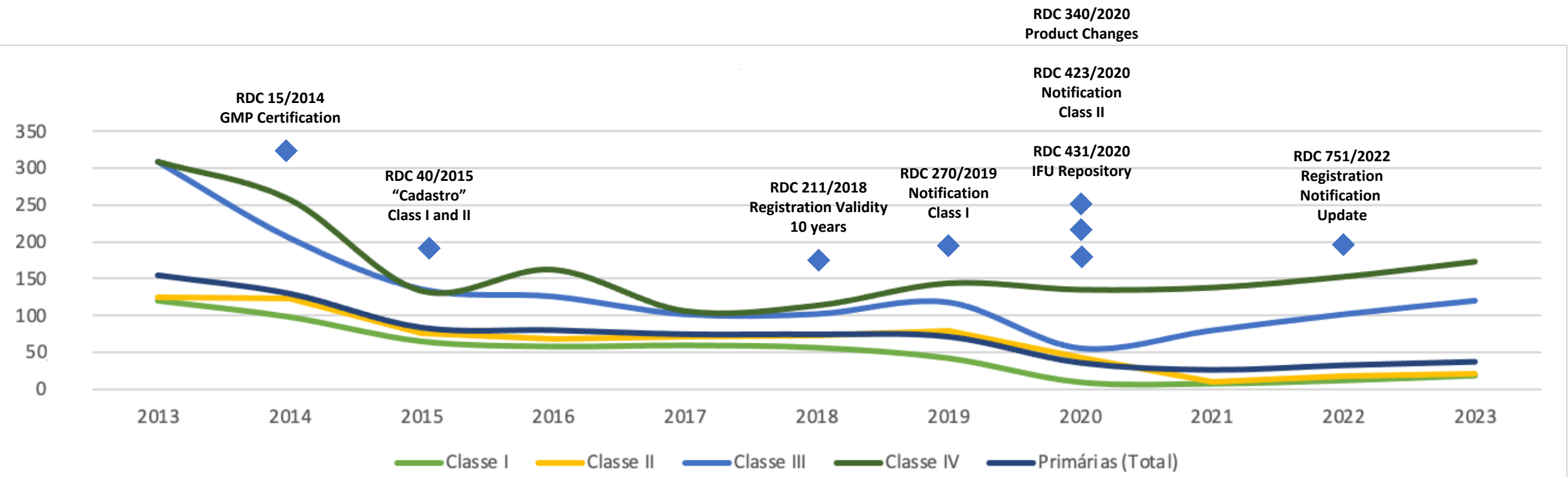
Medical Device Market Authorization



Average Time to Final Decision from ANVISA per Risk Class (days)

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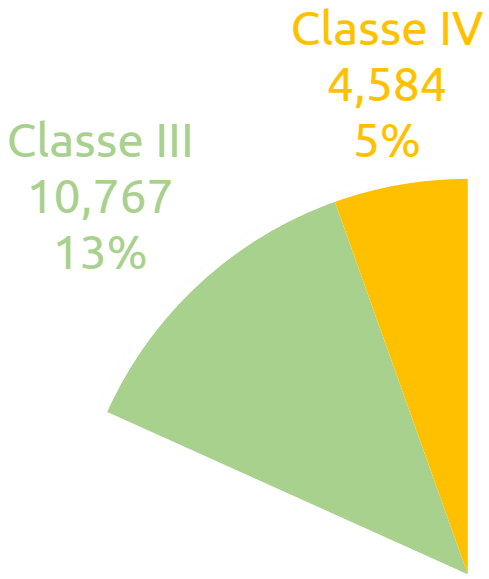
Regulatory Effort



Smallest portion of the universe of medical devices

BUT

Heaviest part of the regulatory pre-market effort

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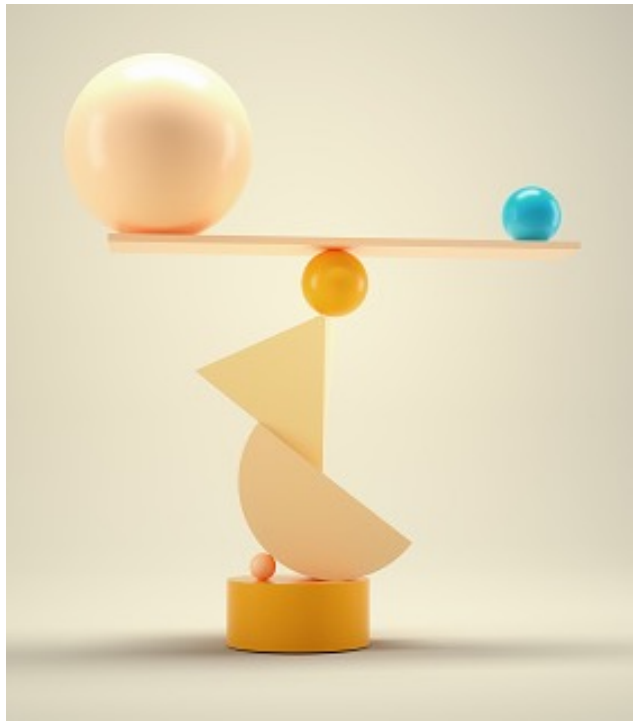
Regulatory Effort



Simplification of work processes for lower risk products

AND

Better use of the workforce

Regulatory Convergence

IMDRF International Medical Device Regulators Forum

MERCOSUL

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

World Health Organization

Bilateral agreements

ISO

IEC

Implementation of IMDRF Documents

Unique Device Identification (UDI)
RDC 591/2021

Update of the Essential Requirements of Safety and Performance
Consolidation of contributions to the public consultation
Harmonization Mercosur
(IMDRF/GRRP WG/N47FINAL:2018)

Update of Medical Devices Risk Classification Rules
GHTF/IMDRF basis – RDC 751/2022

Adoption of the IMDRF ToC as an option of submission format
Regulated Product Submission (RPS)

Implementation of IMDRF Documents

Regulation of Software as a Medical Device (SaMD)
RDC 657/2022

Regulation of Personalized Medical Devices
RDC 305/2019

Clinical Investigation, Clinical Evidence and Clinical Evaluation
Guia 29/2019; 30/2019; and 31/2021

Medical Device Cybersecurity Guide
Guia 38/2020

Medical Device Single Review Program (MDSRP)
Get started

Reliance Mechanism for Pre-Market Authorizations

reliance. *The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible, and accountable for the decisions taken, even when it relies on the decisions, assessments, and information of others.*

(WHO Global Model Regulatory Framework)

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Reliance Mechanism for Pre-Market Authorizations

General Regulation – RDC 741/2022

- Pathway for abridged review process
- Normative Instruction for MD and IVD MD under development (Public Consultation soon)
- Product registration certificates from Equivalent Foreign Regulatory Authorities will be used as a trigger for expedited review

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Reliance Mechanism for Pre-Market Authorizations

- **Conditions that will apply:**
- Agreement on the exchange of confidential
- information with the relied NRA
- Classes III and IV – Registration processes
- Product should be essentially the same
  - Same indications for use
  - Same mfg. sites and legal manufacturer
  - Same “regulatory version”

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Reliance Mechanism for Pre-Market Authorizations

Conditions that will apply:

- Specific Brazilian labeling requirements, instructions for use and certification must be met
- Anvisa may choose to perform the complete analysis of the Technical Dossier
- Anvisa may request clarification on the documents submitted for review

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THANK YOU!
OBRIGADO!

MEDICAL DEVICES OFFICE

Brazilian Health Regulatory Agency
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