GLOBAL REGULATORY PARTNERS

Case Study 71:
Registration of Covid-19 Test Kit in Brazil

Client
European medical device company developing and producing antigen test kits for Covid-19.

Products
SARS-CoV-2 Antibody Test

Product Categories
IVDs/Medical device Class III

Countries of Interest
Europe and USA

Services Offered

- ✓ Local representation in Brazil
- ✓ Gap analysis
- ✓ Medical device classification
- ✓ Regulatory strategy
- ✓ Preparation of technical file
- ✓ Submission of registration dossier to Anvisa.
- ✓ Respond to Anvisa queries

Key Highlights:

- ✓ Classification of SARS-CoV-2 Antibody Test in Brazil
- ✓ Defined the appropriate regulatory strategy for the test kit registration in Brazil
- ✓ Successful submission to Anvisa of registration dossier
- ✓ **100% compliance with Anvisa requirements**
- ✓ GRP continues to be **Strategic Partner in Brazil** for Client

Keywords:

Local representation in Brazil, registration of SARS-CoV-2 Antibody Test in Brazil Anvisa, classification of Covid-19 test kits in Brazil, regulatory strategy Anvisa Brazil.

Client Situation

Client is a European medical device company that develops and manufactures Antigen Test Kits , was looking for a regulatory professional in Brazil that can act as its local representative in Brazil and register with Anvisa an Antigen rapid test kit used for SARS-CoV-2 Antibody testing.

The Covid-19 test kit is intended for the qualitative detection of antibody content against SARS-CoV-2 in clinical samples (serum/plasma/whole blood). The product has a CE mark and sold in Europe.

GRP Solution

Global Regulatory Partners Brazil (GRP Brazil) has a team of regulatory experts in Brazil who has registered successfully many medical devices and IVDs with Anvisa. After receiving the technical information from the client, the team was able to:

1. **Perform a gap analysis of the receive technical information according to Anvisa applicable regulations.**
2. **Determine the classification of the Covid-19 test kit in Brazil.**
3. **Define the regulatory strategy forCovida-19 test kit registration with Anvisa.**
4. **Establish the list of documents and information required for the test kit registration with Anvisa.**
5. **Prepare the registration dossier for test kit according to Anisa regulations.**
6. **Submit successfully the registration dossier for the test kit to Anvisa.**

In Brazil, Covid-19 Test kits are classified as Class III IVDs and their registration needs to comply with resolution governing in vitro diagnostic products is RDC No. 36 of 26 August 2015.

For additional information,
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