DOMO salute
health regulatory consulting

Your Regulatory Affairs partner in Brazil

An Overview on Brazilian Regulatory Agencies' temporary measures to enable market access of COVID-19 related medical devices

17th of April - 2020

DOMO

Our team of regulatory affairs professionals has a wealth of regulatory experience that covers all the requirements related to medical device's registration in

Brazil.

In response to the COVID-19 outbreak, Brazilian medical device market regulators (ANVISA & INMETRO), as well as many other regulators around the world, have released in the past month Ordinances and Resolutions regarding emergency and temporary procedures for devices that are strategic to fight against the pandemic.

The regulations include new temporary regulatory pathways to speed up market access to ventilators, face masks and PPE, test kits, and others.

Those measures intend on preventing shortages in the national market of devices that are needed the most, and also accelerating market entry to foreign manufacturers as well as securing the safety of health care workers, patients and the society.

DOMO Salute is committed to fulfilling our role in the society and working hard to bring quality health solutions closer to people everywhere.

We are working to keep our clients and community updated on the latest moves from Brazilian Regulatory Agencies, and working closely with ANVISA and INMETRO. Count on us to navigate through unstable sea. Stay safe and healthy.

ANVISA's RDC 346/2020
12th of March 2020

ANVISA's first measure was to publish RDC Nº 346/2020, which defines extraordinary and temporary criteria and procedures for GMP Certification, for the purposes of registration and post-registration changes to active pharmaceutical ingredients, medicines and medical devices, due to the international public health emergency of the new Coronavirus.

ALTERNATIVE GMP Pathway

Under the terms of the new Resolution, temporary and emergency use of information from Foreign Regulatory Authorities is allowed to replace Health Inspections carried out by ANVISA.

According to the Resolution, Foreign Regulatory Authority members of the MDSAP (Medical Device Single Audit Program) are the ones entitled to share information for certifications related to medical devices.

In addition, while the Resolution is in force (180 days), the emergency use of remote inspection mechanisms will be temporary allowed, replacing the on-site sanitary inspection for purposes of obtaining GMP Certification. Remote inspections are carried out by means of video-conferencing technologies and data transmission to verify compliance with the GMP. Moreover, remote inspections replace the need for inspectors to be physically present at the productive plant.

Good Manufacturing Practices Certifications granted under the terms of the Resolution will be valid for two years, counting from the publication date in the Brazilian Official Gazette (DOU).

The alternative and temporary certification mechanisms described in the Resolution apply only to petitions submitted prior to the publication of this Resolution, with the exception of the request for GMP certification for medicines or medical devices intended for control, diagnosis, prevention or treatment of the new Coronavirus OR essential products to maintain life, when the availability is threatened by shortages (imminent or installed) in the national market motivated by reason proven to be linked to the new Coronavirus.

It is important to highlight that the Resolution can be renewed for equal and successive periods of 180 days in case inspections by ANVISA are still inviable due to the pandemic.

TEMPORARY GMP Pathway

In case the manufacturer can't comply with the terms previously described, a temporary GMP Certificate can be granted if:

- The medical device is used in cases of serious health risk for the control, diagnosis, prevention or treatment to meet the health needs caused by covid-19 and;
- It is an essential product to maintain life whose availability is threatened by shortages (imminent or installed) in the national market due to the pandemic and;
- GMP Certificate is the only impediment to the registration and commercialization of the product.

It is still necessary to present technical documentation and ANVISA's fee will be still applicable.

Companies certified under the terms of this Resolution may be inspected at any time by ANVISA, which may result in the cancellation of the Certificate issued and the adoption of other restrictive sanitary measures in the event of failure to comply with Good Manufacturing Practices. The Certificate granted under those terms will be valid for 180 days, while the Resolution is valid.

ANVISA's RDC 348/2020
17th of March 2020

Extraordinary procedures for the analysis of applications for the registration of drugs, biological products and in vitro diagnostic products for the prevention and treatment of the new coronavirus (Covid-19).

In order to register IVD products for SARS-CoV-2 diagnosis the manufacturer must comply with the documentation provided for in RDC 36/2015 (Risk classification, control, notification, registration and labeling requirements for IVD products.

The Resolution states that for IVD products processes where performance studies and data restrictions are absent, it must be justified with technical reasons and data that allow the assessment of the reliability of the results and the diagnostic effectiveness of the product.

Aiming to speed products regularization and the offer of diagnostics, ANVISA will prioritize the analysis of all processes related to products for Covid-19 diagnosis and other agents that cause respiratory infections, overlapping the chronological criteria, by signalling the submission to GGVIT.

The measure aims to expand access to IVDs and support health professionals in identifying positive cases.

Registros granted under the conditions of the Resolution will be valid for 1 year, and it will be possible to complement the documentation in order to obtain the regular validity of ***Registros*** in Brazil - 10 years.

ANVISA's RDC 349/2020
19th of March 2020

ANVISA published RDC 349/2020 regarding temporary procedures for requests for the regularization of personal protective equipments, pulmonary ventilator medical equipments and other medical devices identified as strategic by ANVISA due to the international public health emergency resulting from the new Coronavirus.

For situations in which the manufacturing company does not have the Good Manufacturing Practices Certification issued by ANVISA, Medical Device Single Audit Program (MDSAP) or ISO 13485 Quality Management System Certification will be exceptionally accepted.

The proof of registration, free trade certificate or equivalent document, can be replaced by a simple statement issued by the Legal and Technical Responsible of the requesting company informing that the product in question is regulated and marketed in a jurisdiction member of the International Medical Device Regulators Forum (IMDRF) .

Exceptionally, products covered by this Resolution are exempt from certification under the Brazilian Conformity Assessment System (SBAC).

For products subject to this Resolution, necessary declarations for ***Cadastro*** and ***Notification*** petitions are exempt from consularization or Apostille.

Requests for medical devices' registration referred to in this Resolution will be analysed in priority, overriding the chronological criteria.

Regularization may be granted in accordance with this Resolution, when the indication of use is identified to preventing or treating diseases caused by the new Coronavirus (COVID-19). The Resolution will be valid for 180 days.

Registros (high Risk Class) granted under the conditions of the Resolution will be valid for 1 year, and it will be possible to complement the documentation in order to obtain the regular validity of ***Registros*** in Brazil - 10 years.

Notification and Cadastro (low Risk Class) granted under the conditions of the Resolution will be valid for 1 year only.

ANVISA's RDC 356/2020

23rd of March 2020

ANVISA published RDC 356/2020 regarding extraordinary and temporary procedures on the requirements for the manufacture, import and acquisition of medical devices identified as priorities by ANVISA due to the international public health emergency resulting from the new Coronavirus.

The manufacture and import of surgical masks, N95, PFF2 or equivalent particulate respirators, goggles, face shields, disposable hospital garments (waterproof and non-waterproof aprons / cloaks), caps and props, valves, respiratory circuits and connections for use in health services, are exceptionally and temporarily exempt from ANVISA Authorization for Company Operation (AFE), from ***Notification*** to ANVISA, as well as from other health authorizations.

The exemption from health authorization for manufacturers and importers of the products object of this regulation does not exempt:

- The manufacturer and importer to comply with the other requirements applicable to the health control of medical devices, as well as applicable technical standards; and
- The manufacturer and importer to carry out post-market surveillance, as well as to comply with post-market regulations.

The manufacturer or importer is responsible for ensuring the quality, safety and effectiveness of products manufactured in accordance with the regulation.

The purchase of new and not yet regularized by ANVISA personal protective equipments, pulmonary ventilators, respiratory circuits, connections and valves, parametric monitors and other medical devices essential to combat the COVID-19 pandemic, by public and private bodies and entities as well as health services, is as long as they have been previously regularized and marketed in a jurisdiction member of the International Medical Device Regulators Forum (IMDRF). It is only temporarily allowed when similar devices regulated by ANVISA are not available.

Medical devices must be exposed to use with their instructions for use translated into Portuguese when they are essential for the proper functioning of the product.

The health service in which the medical equipment is installed is responsible for the installation, maintenance, traceability and monitoring during the entire useful life of the device, including its disposal.

Specific requirements that must be met for each device is detailed in the Resolution. The Resolution is valid for 180 days.

INMETRO's Ordinance nº 111
27th of March 2020

INMETRO published Ordinance nº 111 regarding extraordinary and temporary procedures for Conformity Assessments, due to the international public health emergency resulting from the new Coronavirus.

The Ordinance establishes alternative conditions for Product Certification Bodies (CBs) to carry out Conformity Assessment activities in manufacturing plants located in countries affected by the coronavirus epidemic (COVID-19), including Brazil.

The Ordinance is only applicable for processes initiated between January 1st 2020 and June 30th 2020. For maintenance or recertification processes, the regulation is effective only if the maintenance/ expiration date of the certificate or registration is within the informed period.

For maintenance and recertification processes, the CB shall perform a risk analysis based on the records of the latest internal audits, top management´s critical analysis and complaints handling, as well as the history of non-conformities in testing. After the analysis, the CB may take the decision to postpone the maintenance or recertification audit.

In the event of the postponement, the Audit must necessarily be carried out within a maximum period of 6 (six) months, counting from the date on which the decision is registered by the CB. Alternatively, based on the risk analysis and considering the existence of adequate conditions, the CB may decide to perform a remote audit.

In the case of remote auditing, the initial, maintenance or recertification audit activity may be performed, at the CB's discretion, dismissing the need for in house audit or scheduling a subsequent in house audit to confirm the certification. If the risk analysis does not support the audit's postponement or if the operating conditions of the factory do not support the performance of remote auditing, the certificate must be suspended.

Regarding testing and test reports, Ordinance 111 gives the possibility for tests to be performed by the manufacturer in 1st or 3rd party laboratories accredited in Brazil or abroad, within the scope of the ILAC Mutual Recognition Arrangement (ILAC MRA), regardless of the lab acceptance criteria provided in the medical device specific Conformity Assessment Requirements.

Regardless of the extraordinary conditions, technical requirements provided for in the regulations published by INMETRO must continue to be complied with by manufacturers.

Summary & Conclusion

ANVISA's RDC 346/2020

Alternative Pathway for BGMP Certification:

- Foreign Regulatory Authority Information (MDSAP)
- Remote auditing

Temporary BGMP Certificate (180 days):

- When BGPM is the single impediment to registration and commercialization

ANVISA's RDC 348/2020

IVD Test's Registration

- Tolerates the absence of studies/ data as long as justified, and the data presented allows the assessment of the reliability of the results and the diagnostic effectiveness of the product.

Validity of 1 year

ANVISA's RDC 349/2020

- Pulmonary Ventilators: exempt from BGMP Certificate - MDSAP or ISO 13485
- FSC waiver: IMDRF
- Ventilators / PPE: exempt from INMETRO's certification
- PPEs: No legalization and sworn translation of the LOA

Validity of 1 year

ANVISA's RDC 356/2020

- PPE: Dismissal of AFE and ***Notification***
- ALL: No need for regularization in the absence of a similar regulated product on the local market or in case of donations (IMDRF jurisdiction).

INMETRO's Ordinance nº 111

- Certification Body: Performs risk analysis based on records from latest internal audits, top management´s critical analysis and complaints handling
- Postponing or performing remote Audits
- Testing and test reports, can be performed by the manufacturer in 1st or 3rd party laboratories accredited in Brazil or abroad.

Authors

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With her background she is able to assist clients with the Brazilian regulatory requirements, having completed many regulatory applications for GMP certification and product registration.

Thatiana Terroso — *Regulatory Affairs & Administrative Manager*

Over the past years she has acquired a profound comprehension of ANVISA's regulatory guidelines. Always able to understand your devices' unique needs and determine the best approach for your regulatory strategy.

Diego Louzada — *Business Development INMETRO/ANATEL specialist*

Eight years assisting companies getting their INMETRO/ANATEL certification and building strong relationships with regulatory agencies.

We take the time to build your project especifically tailored for your regulatory needs.

From day one, you will be talking to a Regulatory Affairs expert and will be informed of the best registration strategy for your product.

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