LATINI GROUP
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Av. Vereador José Diniz, 2.270
São Paulo ● SP ● Brasil/ Brazil
CEP/ Zipcode: 04604-003
Tel./ Phone: 55 11 5090 5080
Fax: 55 11 5090 5083
Site: www.latinigroup.com

RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS – RDC No. 608, OF FEBRUARY 25, 2022

It provides for the compassionate use of medical devices.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the attributions conferred on it by article 15, III and IV, together with article 7, III and IV of Law No. 9,782, of January 26, 1999, and article 187, VI, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, resolves to adopt the following Resolution of the Board of Executive Officers, as resolved at a meeting held on February 23, 2022, and I, the Chief Executive Officer, determine its publication.

CHAPTER I
INITIAL PROVISIONS

Section I
Object

Art. 1 This Resolution provides for the requirements for submission and consent of programs for the compassionate use of medical devices.

Section II
Scope

Art. 2 The criteria established in this Resolution apply to the submission and consent of programs for the compassionate use of medical devices.

Single paragraph. This Resolution does not apply to tailor-made, patient-specific or adaptable medical devices, which continue to be governed by Collegiate Board Resolution - RDC No. 305, of September 24, 2019 or Resolution that may replace it.

Art. 3 Requests for consent of programs for the compassionate use of medical devices are applicable to the following situations, when they occur simultaneously:

1.- patient with severe debilitating disease; and

2.- absence of satisfactory therapeutic alternative in the country for the clinical condition presented; and

3.- benefit-risk ratio favorable to the use of the requested medical device.

Art. 4 The proposed medical device must have a conclusive report based on the scientific literature, clinical data and studies of the respective disease, its evolution or morbid state to be treated and be in the validation phase of the design and development.

Single paragraph. The conclusive report that the caput deals with should contain a favorable benefit-risk analysis, considering the severity of the disease and the unavailability of other therapies and resources.

Section III
Definition

Art. 5 For the purposes of this Resolution, the following definitions are adopted:

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1.- specific special communication for compassionate use of medical device (CEE-UCDM): authorizing document, issued by Anvisa, necessary for the execution of a program of compassionate use in Brazil of a medical device not yet registered with Anvisa and, when applicable, for the importation of the medical device to be used in the compassionate use program;

2.- severe debilitating disease: one that substantially impairs its carriers in the performance of tasks of daily living and chronic disease that, if left untreated, will progress in most cases, leading to cumulative losses of autonomy, sequelae or death;

3.- attending physician: physician who establishes the justification for the use of the medical device through a technical report, prescribes, assists the patient and is responsible for providing care in the occurrences related to the specific intervention and respective surgical clinical follow-up;

4.- representative organization of the sponsor (ORP): company regularly installed in the national territory, including representative organizations of clinical research (ORPC), educational institutions and hospitals, contracted by the sponsor, which partially or totally assumes the attributions of the sponsor with Anvisa;

5.- sponsor: individual or legal entity, public or private, who financially supports the programs of compassionate use of medical device;

6.- program of compassionate use of medical device: availability of innovative medical device not yet registered with Anvisa, for the exclusive use of patients, which is in the process of validation, intended for patients with severe debilitating diseases and/or that threaten life and without satisfactory therapeutic alternative with products registered in the country; and

7- instructions for use: document containing information provided by the manufacturer to clarify to the user about the intended purpose of a device, its correct use and any precautions.

CHAPTER II
PROCEDURES

Section I
Request and Consent

Art. 6 The request for adherence to the program of compassionate use of medical device must be made by the sponsor or ORP, through a specific administrative process.

Art. 7 The request and consent for compassionate use of medical device is personal and non-transferable, not being allowed the formation of groups and / or inclusion of patients in the same request.

Art. 8 The consent to the programs of compassionate use of medical devices by Anvisa will be given through the issuance of the special specific communication for compassionate use of medical device (CEE-UCDM).

Art. 9 The submission dossier must consist of the following documents:

I.- Petition form for Program for Compassionate Use of Medical Device duly completed and signed by the legal representative of the sponsor, according to the model form provided for in Annex I of this Resolution;

II- Patient Presentation Form for Compassionate Use of Medical Device duly completed and signed by the attending physician, with adequate clinical justification including the description of the severity of the patient's clinical condition, the previous treatments, the reason for the non-suitability for use of approved products and the schedule of intervention and follow-up according to the model form provided for in Annex II of this Resolution;

III- Statement of Responsibility and Sponsor Commitment form - Compassionate Medical Device Use Program signed by the sponsor's legal representative, as per the model form set forth in Annex III to this Resolution;

IV- form of Declaration of Responsibility and Commitment of the Physician signed by the attending physician, according to the model form provided for in Annex IV of this Resolution;

V- Curriculum Lattes of the Attending Physician;

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VI.- safety and efficacy data sufficient to support the indication for use of the medical device, which may be, but is not limited to, clinical evaluation reports, clinical investigation reports and copies of the reference articles from which the reports were obtained; and

VII- copy of the patient's information and adherence term, according to Annex V of this Resolution, signed by the patient who will enjoy the compassionate use or by the legal representative.

§ 1º the level of evidence of the references referred to in item VI can vary from randomized controlled trials, non-randomized trials, case reports to consensus opinion.

§ 2º the level of evidence required of the reference articles referred to in item VI will depend on the severity of the disease, using, but not limited to, technical standards, clinical guides or reference regulations.

Section II
Product identification

Art. 10. The label of medical devices for use in compassionate use programs should contain the following information:

I- information necessary for identification of the medical device by the user;

II- contents of the package, special conditions of storage, storage and/or handling of the medical device, equivalent symbology may be used;

III- Validity of the product, as applicable;

IV- identification of the patient by the initials of the full name;

V- identification of the attending physician by means of the registration number in the professional council;

VI- batch number or serial number for device tracking; and

VII- Say mandatory: "Medical device for compassionate use program".

Single paragraph. The label of medical devices for use in compassionate use programs may be affixed after the entry of the product in Brazil.

CHAPTER III
DUTIES AND RESPONSIBILITIES

Art. 11. The sponsor or ORP shall provide the medical device free of charge and ensure the supply of the product for as long as there is benefit to the patient or at the discretion of the authorized attending physician in the respective compassionate use of medical device program.

Section I
Sponsor Assignments

Art. 12. The sponsor's duties are:

I -provide free of charge the medical device object of the medical device use program(s) for as long as there is benefit from the intervention, at the discretion of the attending physician;

II- be responsible for the device to be used in the program(s) compassionate use of medical device, keeping it properly stored until its distribution;

III.- maintain monitoring and records of the product(s) delivered to the attending physician and the remaining physical stocks in its storage, for possible inspection by Anvisa;

IV.- notify Anvisa of serious adverse events, through the form available on Anvisa's website, within a maximum period of 15 (fifteen) calendar days from the knowledge of the fact, except for cases involving death of the patient in which the notification must occur in a maximum of 7 (seven) calendar days;

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V.- provide the financial resource of comprehensive care for complications and/or damages arising from the anticipated and unforeseen risks related to the use of the medical device object of the program(s) of compassionate use of medical device; and

VI.- ensure that the medical device in compassionate use is produced in accordance with the Good Manufacturing Practices established in Brazilian or similar standards.

Art. 13. The sponsor or the ORP is prohibited from marketing the medical device object of the programs compassionate use of medical device.

Section II
Duties of the Attending Physician

Art. 14. The duties of the attending physician are:

I.- make a formal request for the product to the sponsor, for each patient to be treated, justifying the use through a medical report;

II.- properly store the medical device according to the manufacturer's instructions for use;

III.- notify the sponsor or ORP of the occurrence of serious adverse events within 24 (twenty-four) hours from the knowledge of the fact;

IV.- provide the sponsor or ORP with the necessary documentation for the monitoring of compassionate medical device use programs;

V.- develop appropriate timeline for patient monitoring, taking into account the investigational nature of the device and the specific needs of the patient;

VI.– monitor the patient to detect possible problems arising from the use of the device;

VII.- assume responsibility for medical care in case of complications and/or damages arising from the risks foreseen and not foreseen in the program(s) of compassionate use of medical device; and

VIII.- notify sponsor of any change to the original "compassionate use of medical device" process within seven (7) calendar days.

CHAPTER IV
MONITORING

Art. 15. The sponsor or contracted ORP shall forward to Anvisa, on an annual basis, individualized reports per patient on the program(s) of compassionate use.

Single paragraph. The annual submission of the reports referred to in the caput will begin with the consent of the process by Anvisa and must be in accordance with the intervention and follow-up schedule established for the patient described in the "Patient Presentation Form for Compassionate Use of Medical Device".

Art. 16. Within 90 (ninety) days after the end of the program, the sponsor or the contracted ORP must send Anvisa a final report.

Art. 17. Safety and efficacy data collected during compassionate use programs will not replace clinical investigations for medical device registration purposes.

§ 1º the safety and efficacy data referred to in the caput may be sent by the company as additional data at the time of submission of the product registration.

§ 2º the safety and efficacy data submitted must not contain identification and/or personal data that identifies patients.

Art. 18. Compassionate use of medical device programs should not delay the execution of clinical investigations.

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CHAPTER V
OF THE AMENDMENTS

Art. 19. The sponsor or the contracted ORP shall notify Anvisa, in addition to the original "compassionate use of medical device" process, of any change regarding the program(s) of compassionate use of medical device.

§ 1º The sponsor or the ORP must wait for the positioning of Anvisa, for the implementation of the changes referred to in the caput.

§ 2º Except for the determination of the first paragraph of amendment whose purpose is to safeguard the safety of patients, a situation that needs to be promptly notified to Anvisa.

Art. 20. The notification of change of the attending physician must be instructed with the following documents:

I - Petition form for Program for Compassionate Use of Medical Device duly completed and signed by the legal representative of the sponsor, as provided in Annex I of this Resolution;

II- Declaration of Responsibility and Sponsor Commitment form - Program for Compassionate Use of Medical Device signed by the legal representative of the sponsor, as provided in Annex III of this Resolution;

III.- letter with transfer term of the attending physician authorized by Anvisa, transferring patient care to the new doctor;

IV.- letter from the new attending physician assuming the commitment to care for the patient;

V.- curriculum vitae or Lattes of the new attending physician;

VI.- letter signed by the patient or his legal representative, acknowledging knowledge about the change of attending physician; and

VII.- copy of CEE-UCDM.

Art. 21. The notification of change of the institution in which the treatment will be carried out must be instructed with a letter signed by the patient or his legal representative acknowledging knowledge of the change of institution.

CHAPTER VII
OF THE FINAL PROVISIONS

Art. 24. To import products intended for programs of compassionate use of medical devices, the provisions of Chapter XXVI of the Collegiate Board Resolution - RDC No. 81, of November 5, 2008 or Resolution that may replace it, must be complied with.

Art. 25. Anvisa may, during programs for the compassionate use of medical devices, request additional information from those responsible for their execution or monitoring and carry out inspections in order to verify compliance with current Brazilian legislation and the approved program.

Art. 26. Failure to comply with the definitions and rules provided for in this regulation constitutes a health infraction under the terms of Law No. 6,437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liability.

Art. 27. This Resolution shall enter into force on the date of its publication.

ANTONIO BARRA TORRES
Chief Executive Officer

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ANNEX I
MEDICAL DEVICE COMPASSIONATE USE PROGRAM PETITION FORM

	National Health Surveillance Agency Compassionate Medical Device Use Program Petition Form		
Applicant/ORP Data			
1	Corporate Name	2	Commercial name
3	Address	4	City
5	Telephone	6	email:
7	State	8	CNPJ
Sponsor Data			
9	Corporate Name	10	Commercial name
11	Address	12	City
13	Telephone	14	email:
15	State/country	16	CNPJ
Medical Device Data			
17	Technical name:	18	Risk class: ( ) Class I ( ) Class II ( ) Class III ( ) Class IV

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19	Medical device characterized as: ( ) Material for Use in Health ( ) Equipment ( ) In vitro diagnostic product		
20	Trade name (if applicable):		
21	Stage of development of the medical device (please specify):		
22	Clinical indication:		

Compassionate Usage Data

23	Title:	24	Countries where the medical device has been used as a compassionate use(if applicable):

Disclaimer

In this act represented by its legal representative, the sponsor assumes civilly and criminally, full responsibility for the information provided herein, as well as for the quality of the product (s) to be used in the compassionate use program presented herein, including in appropriate cases, its sterility and / or apirogenicity.

~~Legal Representative of the Sponsor~~
(Signature, Date and Stamp)

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ANNEX II
PATIENT PRESENTATION FORM FOR COMPASSIONATE USE OF MEDICAL DEVICE

		National Health Surveillance Agency Patient Presentation Form for Compassionate Medical Device Use		
Sponsor Data				
1	Corporate Name	2		Commercial name
3	Address	4		City
5	Telephone	6		email:
7	state	8		CNPJ
Data of the Attending Physician				
9	Name	10	Regional Council of Medicine Number (CRM):	
11	Institution where the treatment will be carried out:	12	CNES:	
13	Address:	14	email:	
Compassionate Use Program Data				
15	Título:			
16	Description of the medical device for compassionate use:			
Patient Data				
17	Full name initials:			
18	Sex ( ) M ( ) F	19		Date of Birth or Age:
20	Address:	21		Phone and or email:
22	Clinical justification for the use of the medical device (including assessment of the severity of the patient's condition, previous treatments that did not control the disease and benefit-risk analysis in the use of the requested product and the schedule of intervention and follow-up of the patient)			

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Disclaimer

In this act I assume civilly and criminally, full responsibility for the information provided herein.

Attending Physician
(Signature, Cata and Stamp)

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ANNEX III
SPONSOR DISCLAIMER AND COMMITMENT FORM MEDICAL DEVICE COMPASSIONATE USE PROGRAM

	National Health Surveillance Agency Sponsor Declaration of Responsibility and Commitment Form Compassionate Device Use Program Doctor		
Sponsor Data			
1	Name:		
2	Address:	3	email:
4	Telephone:	5	Medical Device Name for Compassionate Use Program:
6	Intended Use:		
7	Title of the Compassionate Use Program:		
Responsibilities			
8	The SPONSOR, through its undersigned legal representative, declares to be responsible in Brazil for the conduct of the compassionate use program entitled: "xxxxxxxxxxxxxxx", and assumes before the National Health Surveillance Agency – Anvisa, by this declaration, the following responsibilities: I -provide free of charge the medical device object of the programs of compassionate use of medical device while there is benefit of the intervention, at the discretion of the attending physician; II - be responsible for the medical device to be used in the compassionate use of medical device programs, keeping it properly stored until its distribution; IV - maintain monitoring and records of the products delivered to the attending physician of the remaining physical stocks in their storage, for possible inspection by Anvisa;		

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	V - notify Anvisa of serious adverse events, through the form available on Anvisa's website, within a maximum period of 15 (fifteen) calendar days, from the knowledge of the fact, except for cases involving death of the patient in which the notification must occur in a maximum of 7 (seven) calendar days; VI - provide the financial resources of comprehensive care for complications and/or damages arising from the anticipated and unforeseen risks related to the use of the medical device object of the programs of compassionate use of medical device; VII - ensure that the medical device in compassionate use is produced in accordance with the Good Manufacturing Practices established in Brazilian or similar standards; and VIII – Do not market the medical device object of the programs compassionate use of medical device.
	_____ Sponsor or Legal Representative (Signature and Date)

ANNEX IV
PHYSICIAN ASSISTANT STATEMENT OF RESPONSIBILITY AND COMMITMENT FORM MEDICAL DEVICE COMPASSIONATE USE PROGRAM

	National Health Surveillance Agency Assistant Physician Declaration of Responsibility and Commitment Form Compassionate Medical Device Use Program		
Data of the Attending Physician			
1	Name:	2	Registration Number with the Regional Council of Medicine (CRM):
3	Institution where the treatment will be carried out:	4	CNES of the institution:
5	Address:	6	email:

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Compassionate Use Program Data

7	Title:
8	Medical device for compassionate use:

Responsibilities

I agree on :
make a formal request for the product to the sponsor, for each patient to be treated, justifying the use through a medical report, if you are interested in having patients in the programs of compassionate use of medical device;
properly store the medical device according to the manufacturer's instructions for use;
notify the sponsor or ORP of the occurrence of serious adverse events within twenty-four (24) hours of knowledge of the fact;
provide the sponsor or ORP with the necessary documentation for the monitoring of compassionate medical device use programs;
devise an appropriate schedule for monitoring the patient, taking into account the investigational nature of the device and the specific needs of the patient; monitor the patient to detect possible problems arising from the use of the device;
assume responsibility for medical care in the event of complications and/or damages arising from the risks foreseen and not foreseen in the programs of compassionate use of medical devices; and
notify sponsor of any changes to the original "compassionate use of medical device" process within 7 calendar days.

I assume civilly and criminally the veracity of the information presented herein.

_____

Attending Physician
(Signature, Stamp and Date)

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ANNEX V
TERM OF INFORMATION AND PATIENT ADHERENCE

Document to be prepared by the sponsor, to be used in a standardized manner by all physicians participating in the programs of compassionate use of medical device. To be drafted in accessible language and containing the following elements:

a) information that it is a product not yet registered with Anvisa and, therefore, not marketed in Brazil;

b) whereas this is not a clinical trial, but a new therapeutic resource whose efficacy and safety are still under evaluation, and which is being made available to you by the sponsor, who should be identified;

c) the justification for the use of the product in the patient;

d) the possible discomforts and risks including adverse effects and expected benefits;

e) the existing alternative methods and why they do not meet the patient's condition;

f) that the physician knows the product sufficiently in relation to the expected therapeutic effects, as well as the possible adverse effects that may occur with its use;

g) that the treatment and its results will be managed within the doctor-patient relationship, with the ethics and confidentiality required by it;

h) that patient personal data obtained, collected and/or accessed will be treated in compliance with applicable data protection laws, only for the purposes set forth herein and as necessary for evaluation of product safety and efficacy data, and may be shared by Sponsor only with health authorities for purposes of complying with regulatory and product registration obligations.

i) that the patient has the freedom to accept or refuse this new therapeutic resource at any time;

j) that the product is being provided free of charge to the patient for the period determined in this Resolution. The physician responsible (attending physician) for the treatment of the patient must provide, before using the product of the programs compassionate use:

1.detailed explanation of the term of information and adherence of the patient, clarifying any doubts that the patient may have;

2.that the patient, or his legal representative, in his own hand, write his name and number of the identity document in the term of information and adherence of the patient;

3.that the patient or his/her legal representative sign and place the date in the patient's information and adherence term. If the signature is replaced by a fingerprint, the identification and signature of a witness shall be obtained;

4.signature of the attending physician and date in the term of information and adherence of the patient;

5.keep in their files one copy of the patient's information and adherence term and provide another copy to the patient or their legal representative, both with the data and signatures described above.