

## **RESOLUTION 305\_19 - RDC N° 305, OF SEPTEMBER 24, 2019**

It sets out requirements for the manufacture, marketing, import and exposure to the use of personalized medical devices.

The Collegiate Board of the National Health Surveillance Agency, in the use of the competences that confer on it the arts. 7, item III, and 15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of article 53, item VI and §§ 1 and 3, of the Internal Regulations, approved by the Collegiate Board Resolution – RDC No. 255, of December 10, 2018, resolves to adopt the following Resolution of the Board of Directors, as resolved at a meeting held on August 30, 2021, and I, the Chief Executive Officer, determine its publication.

### **CHAPTER I**

#### **INITIAL PROVISIONS**

Art. 1º The purpose of this Resolution is to define the requirements for the manufacture, marketing, import and exposure to the use of personalised medical devices.

Single paragraph. This Resolution shall not apply to active medical devices, in vitro diagnostic products, medical devices intended for clinical research, custom-made products in technical orthopaedic and orthopaedic lime manufacturing undertakings, and dental services provided by a qualified professional.

Art. 2º For the purpose of this resolution, the following definitions shall apply:

1 - consent to the manufacture or import of a custom-made medical device: an act of ANVISA which, after a formal and technical analysis of a request requested by the interested party, agrees with the manufacture, marketing, importation and exposure to the use of tailor-made medical devices;

2 - personalized medical device: a generic term to describe any of the types of medical devices intended for a particular individual, which may be a custom-made medical device, a specific patient-specific medical device or an adaptable medical device;

3 - tailor-made medical device: a medical device intended exclusively for use by a particular individual, manufactured specifically in accordance with the prescription of a qualified health professional, which confers specific design characteristics under his responsibility, even if the design can be developed jointly with the manufacturer. Such a product is intended to meet a specific anatomophysiological pathology or condition of a particular individual.

4 - patient-specific medical device: a medical device which is made compatible (or compatible) with a patient's anatomy using sizing techniques based on anatomical references, or using anatomical characteristics obtained from imaging examinations, and is typically produced in batch by means of a process capable of being validated and reproduced, Under the responsibility of the manufacturer, even if the project can be developed in conjunction with the qualified SA professional;

5 - adaptive medical device: a mass-produced medical device which must be adapted, adjusted, assembled or moulded in accordance with the manufacturer's validated instructions at the point of care to suit the specific anatomophysiol characteristics of a patient prior to use;

6 - notification of manufacture or import of custom-made medical device: act of notifying ANVISA of the intention to manufacture or import custom-made medical device of classes III and IV, as classified in the Resolution of the Collegiate Board - RDC No. 185, of October 22, 2001, or in its updates;

7 - single number of screening: combination of numeric or alphanumeric levels, from which the complete history of purchases, manufacture, packaging, labelling and distribution of the finished product can be determined; and

8 - manufacturing plant: place where the manufacture or stage of manufacture of the products takes place, which may be the legal manufacturer itself, contracted manufacturer or original equipment manufacturer (OEM).

Art. 3<sup>o</sup> The adaptable medical device and the specific patient medical device are subject to regularization at Anvisa according to the criteria established in the Resolution of the Collegiate Board - RDC No. 185, of 2001, and in the Resolution of the Collegiate Board - RDC No. 40, of August 26, 2015, and other regulations in force.

Art. 4 - Tailor-made medical devices, although they do not depend on registration or registration with ANVISA, in the form of the Resolution of the Collegiate Board - RDC No. 185, of 2001, and the Resolution of the Collegiate Board - RDC No. 40, of 2015, are subject to sanitary control prior to introduction to the market by means of consent to manufacture or import and notification of manufacture or import, as provided in this Resolution.

## **CHAPTER II**

### **REGULARIZATION MEDICAL DEVICES ADJUSTMENT**

Art. 5<sup>o</sup> Manufacturers or importers of tailor-made medical devices must have an Operating Authorization granted by ANVISA and sanitary licensing issued by the local health surveillance, under the terms of Law No. 6,360, of September 23, 1976, and Decree No. 8,077, of August 14, 2013, and current regulations.

Art. 6 The medical devices tailored must meet the requirements of safety and effectiveness established in the Resolution of the Collegiate Board - RDC No. 56, of 6 April 2001 or its updates, as well as the applicable technical standards and norms.

Art. 7 The establishments that manufacture custom-made medical devices in classes III and IV, as classified in the Resolution of the Collegiate Board of Directors - RDC No. 185, of 2001 or its updates, must have a Certificate of Good Manufacturing Practices issued by ANVISA valid for the risk class of the device.

Art. 8 The establishments that manufacture custom-made medical devices in classes I and II, as classified in the Resolution of the Collegiate Board of Directors - RDC No. 185, of 2001 or its updates, must meet the requirements of Good Manufacturing Practices of Products for Health.

Art. 9 The national manufacturer or importer of custom-made medical devices falling within classes III and IV must file with ANVISA, once, a primary petition regarding the request for

consent to the manufacture or import of medical device tailored for each manufacturing unit containing:

I - Declaration of responsibility of the manufacturer or importer of custom-made devices, duly completed and signed in accordance with Annex II;

II - proof of valid registration with ANVISA of medical devices manufactured on a commercial scale, in the same manufacturing unit, with the same risk class and indicates the use of the tailor-made medical device; and

III - Certificate of Good Manufacturing Practices for products for the manufacturing plant where the custom-made medical device will be manufactured and valid for the risk class of the device, or the renewal protocol of the Certificate of Good Manufacturing Practice, provided that the last report is satisfied.

§ 1º The petition referred to in the caput must be filed with ANVISA at least thirty (30) days in advance of the manufacture or import of the first device from the validity of this Resolution.

§ 2º - ANVISA will carry out the analysis of the petition referred to in the caput, and the decision will be published on ANVISA's electronic portal, as well as will be communicated to the company through an electronic document.

Art. 10 The holder of the consent to the manufacture or import of a custom-made medical device shall file prior to its manufacture, in the form of a petition secondary to consent, notification of manufacture or import for each custom-made medical device falling within classes III and IV, contemplating:

- I. - the petition form for a custom-made medical device, as provided for in Annex III, for each device manufactured or imported, duly completed and signed;
- II. - the statement of responsibility and clarification for the exceptional use of the custom-made device, as Annex I, for each device manufactured or imported, duly completed and signed;
- III. Report of the professional of SA of competent prescriber in which it states:
  - a) signature of the professional of Sa de and registration in the professional council;
  - b) leg vel;
  - c) identification of the patient (full name and CPF, or other identification document in the absence of the CPF);
  - d) name of the pathology and its ICD; and
  - e) description of the case and justification for the use of a product not registered in Brazil in comparison with existing therapeutic alternatives registered by Anvisa and previous treatments.

I - a custom-made technical drawing of the medical device which makes it possible to visualize the product and its components and to identify its characteristic dimensions, tolerances and surface finish, and for each component the information on the manufacturing material and its respective technical standard must be included; and

II - Certificate of Good Manufacturing Practice for the manufacturing plant where the medical device was manufactured, for the risk class of the product valid during the period of manufacture of the custom-made medical device, or of the renewal protocol for the Certificate of Good Manufacturing Practice, provided that the last report is satisfied.

Art. 11 In order to manufacture or import custom-made medical devices, the domestic

manufacturer or importer of a custom-made medical device shall maintain a dossier for each device comprising the following documents:

I - Report of the professional of SA of competent prescriber in which it states:

- a) Legible signature of the professional of Sa de and registration in the Professional Council;
- b) identification of the patient (full name and CPF, or other identification document in the absence of the CPF);
- c) name of the pathology and its ICD; and
- d) description of the case and justification for the use of a product not registered in Brazil in comparison with existing therapeutic alternatives registered by Anvisa and previous treatments.

I - digitized examination of imaging examinations duly reported, where applicable, on which the description of the case and the justification for the use of the custom-made medical device are based;

II - Disclaimer and clarification for exceptional use of the tailor-made device, as Annex I;

III - manufacturing flowchart, which consists of a brief description of each stage of the manufacturing process, up to the production of the finished product, specifying all the manufacturing units (company name and address) that participate in the process and relating them to the manufacturing steps. In the case of manufacture abroad, inform the name and address of the manufacturer responsible and the manufacturing unit(s) of each stage of manufacture;

IV - a tailor-made technical drawing of the medical device which makes it possible to visualize the product and its components, as well as to identify its dimensions, characteristics, tolerances and surface finish, and for each component the information on the manufacturing material and its respective technical standard must be included;

V - The Certificate of Good Manufacturing Practice for the manufacturing plant where the medical device was manufactured, for the risk class of the product, which must be valid during the period of manufacture of the custom-made medical device, or the protocol for the renewal of the Certificate of Good Manufacturing Practice provided that the last report is satisfactory;

VI - copy of Import Licence in the case of imported custom-made medical device;

VII - Petition form, in accordance with Annex III to this Resolution; and IX - c sink of the r tulo applied to the product.

§ 1º The dossier of custom-made implantable medical devices must be kept in the company for a period of not less than fifteen (15) years from the date of manufacture.

§ 2º The dossier of custom-made non-implantable medical devices must be kept in the company for a period of not less than five (5) years from the date of manufacture.

Art. 12 The holder of the consent to the manufacture or import of a custom-made medical device shall maintain documentation ensuring traceability of the medical device to the patient.

Art. 13 Custom-made implantable medical devices in classes III and IV shall be made available with at least three (3) traceability labels containing the following information:

I.- identification of the product, followed by "medical device under measure".

II - identification of the domestic manufacturer or importer (CNPJ and Reason Social);

III - mere number of product traceability;

IV - identification of the patient (initials of the full name); and

V- identification of the professional person in charge, followed by the number of members of the professional council.

Single paragraph. Traceability labels must be affixed to the medical record filed in the service of which the patient was treated, in the document to be delivered to the patient, and in the tax documentation that generates the charge.

Art. 14 The content of tailor-made medical devices must meet the applicable requirements set forth in Annex III-B of the Resolution of the Collegiate Board of Directors – RDC No. 185 of 2001 or its updates, and contains the following information:

I - identification of the patient (initials of the full name);

II - identification of the professional of the prescriber, followed by the number of registration with the professional council;

III - Mere tracking of the device;

IV - no mere of the file of the notification of manufacture or import of the custom-made medical device at Anvisa; and

V - Words "Tailor-made medical device".

Art. 15 The holder of the consent to the manufacture or import of a tailor-made medical device must comply with the technovigilance requirements established in the Resolution of the Collegiate Board of Directors - RDC No. 67, of December 21, 2009 or its updates, and the field requirements established in the Resolution of the Collegiate Board of Directors - RDC No. 23, of 4 April 2012, or its updates.

Art. 16 The holder of the consent to the manufacture or import of a custom-made medical device shall be responsible for ensuring the quality, safety and efficacy of the custom-made medical device.

### **CHAPTER III TRANSIT AND FINAL PROVISIONS**

Art. 17 Manufacturers and importers of specific patient medical devices shall comply with the provisions of Article 3 within twenty-four (24) months from the date of entry into force of this Resolution.

Single paragraph. During the transitional period laid down in the caput, undertakings shall fully comply with the requirements laid down in this Resolution for the manufacture, import, market or display for use of specific patient-specific medical devices.

Art. 18 Anvisa will establish a program for the supervision and monitoring of tailor-made medical devices.

Single paragraph. The programs will be planned considering the operational capacity of the Agency.

Art. 19 Anvisa can, at any time, order the manufacturer/importer to present additional documents and information regarding the medical devices covered by this Resolution.

Art. 20 Non-compliance with the definitions and rules provided for in this regulation for submitting notifications of custom-made medical devices constitutes a sanitary infraction under the terms of Law No. 6,437, of August 20, 1977, without prejudice to civil, administrative and applicable criminal.

Art. 21 This Resolution takes effect thirty days after the date of its publication.

**WILLIAM DIB**

**ATTACHMENT I**

<p><b>TERMO DE RESPONSABILIDADE E ESCLARECIMENTO PARA A UTILIZAÇÃO EXCEPCIONAL DO DISPOSITIVO MÉDICO SOB MEDIDA DE FABRICAÇÃO NACIONAL</b></p>
<p><u>A ser preenchido pelo profissional de saúde :</u> Eu, _____, registrado no conselho profissional _____ sob o número _____ telefone _____ e-mail _____ sou o responsável pelo tratamento e acompanhamento do (a) paciente _____ do sexo _____, com idade de _____ anos completos, com diagnóstico de _____, CID: _____, para quem estou indicando o dispositivo médico sob medida _____, fabricado pela empresa _____ (CNPJ _____) por entender que esta é uma melhor opção terapêutica em relação ao uso de produtos regularizados na Anvisa.</p>
<p>Declaro que informei ao paciente/responsável legal que este produto <u>não possui registro no Brasil</u> , portanto não possui a sua segurança e eficácia avaliada pela Anvisa, podendo causar reações adversas inesperadas ao paciente</p>
<p>_____, ____ de _____, de _____</p> <p>Local e data</p>
<p>Assinatura e carimbo do(a) profissional de saúde Número de Inscrição do Conselho Profissional</p>
<p><u>A ser preenchido pelo paciente ou responsável legal:</u> Eu, _____, (paciente / responsável legal pelo paciente acima citado), carteira de identidade nº _____, órgão expedidor _____, CPF nº _____, residente à _____ bairro _____ cidade _____ estado _____ telefone _____; e-mail _____ recebi pessoalmente as informações do(a) prescritor(a) sobre o tratamento e:</p>
<p>declaro que entendi as orientações recebidas, incluindo as restrições e recomendações de uso, prestadas pelo profissional de saúde e estou de acordo com a proposta de utilização excepcional de dispositivo médico sob medida do tratamento indicado.</p>
<p>_____, ____ de _____, de _____</p> <p>Local e data</p>
<p>Assinatura</p>
<p><b>TERMO DE RESPONSABILIDADE E ESCLARECIMENTO PARA A UTILIZAÇÃO EXCEPCIONAL DO DISPOSITIVO MÉDICO SOB MEDIDA IMPORTADO</b></p>
<p><u>A ser preenchido pelo profissional de saúde:</u> Eu, _____, registrado no conselho profissional _____ sob o número _____ telefone _____ e-mail _____ sou o responsável pelo tratamento e acompanhamento do (a) paciente _____ do sexo _____, com idade de _____ anos completos, com</p>

diagnóstico de \_\_\_\_\_, CID: \_\_\_\_\_, para quem estou indicando o dispositivo médico sob medida \_\_\_\_\_, importado pela empresa \_\_\_\_\_ (CNPJ \_\_\_\_\_), fabricante responsável \_\_\_\_\_

endereço \_\_\_\_\_ e unidade fabril \_\_\_\_\_ endereço \_\_\_\_\_ por entender que esta é uma melhor opção terapêutica em relação ao uso de produtos regularizados na Anvisa.

Declaro que informei ao paciente/responsável legal que este produto não possui registro no Brasil, portanto não possui a sua segurança e eficácia avaliada pela Anvisa, podendo causar reações adversas inesperadas ao paciente.

\_\_\_\_\_, \_\_\_\_ de \_\_\_\_\_, de \_\_\_\_\_

Local e data

Assinatura e carimbo do(a) profissional de saúde  
Número de Inscrição no Conselho Profissional

A ser preenchido pelo paciente ou responsável legal:

Eu, \_\_\_\_\_, (paciente / responsável legal pelo paciente acima citado), carteira de identidade nº \_\_\_\_\_, órgão expedidor \_\_\_\_\_, CPF nº \_\_\_\_\_, residente à \_\_\_\_\_ bairro \_\_\_\_\_ cidade \_\_\_\_\_ estado \_\_\_\_\_, telefone \_\_\_\_\_,

e-mail \_\_\_\_\_, recebi pessoalmente as informações do(a) prescritor(a) sobre o tratamento e:

declaro que entendi as orientações recebidas, incluindo as restrições e recomendações de uso, prestadas pelo profissional de saúde e estou de acordo com a proposta de utilização excepcional de dispositivo médico sob medida do tratamento indicado.

\_\_\_\_\_, \_\_\_\_ de \_\_\_\_\_, de \_\_\_\_\_

Local e data

Assinatura

## ATTACHMENT II

### DECLARATION OF RESPONSIBILITY OF THE HOLDER OF CONSENT OF A CUSTOM MEDICAL DEVICE

National Manufacturer or Importer Data

Razão Social		
Endereço	CNPJ	
Cidade	UF	CEP
Telefone		
E-mail		
Responsável Técnico		
Responsável Legal		
Autorização de Funcionamento		

Atividades ( ) Fabricar ( ) Importar	
Identificação dos tipos de dispositivos médicos sob medida a serem fabricados	Nº de notificação/cadastro/registro do dispositivo médico com mesma classe de risco e indicação de uso
1)	
2)	
...	

A empresa, nas pessoas de seus responsáveis legais e técnicos, assegura e é responsável pelo cumprimento dos requisitos estabelecidos na regulamentação aplicável para a fabricação, importação, comercialização e exposição ao uso de dispositivos médicos sob medida, bem como pelas informações aqui fornecidas, estando ciente de que é responsável pela eficácia e segurança dos dispositivos por ela fabricados/importados.

\_\_\_\_\_, \_\_\_\_ de \_\_\_\_\_, de \_\_\_\_\_

Local e data

\_\_\_\_\_  
Nome do responsável técnico do titular da autorização

\_\_\_\_\_  
Nome do responsável legal do titular do consentimento

### ANNEX III

#### TAILOR-MADE MEDICAL DEVICE NOTIFICATION FORM

##### 1. Tailor-made medical device data

Nome comercial	
Nome técnico	
Regra de classificação	Classe de risco
Número de rastreio	
Data de fabricação	
Matéria prima do dispositivo e respectiva norma técnica	
Região anatômica de implantação	

##### 2. Origem do dispositivo médico sob medida

Nome do Fabricante Responsável  
Endereço

País
Nome da Unidade Fabril
Endereço
País

3. Dados do paciente

Nome completo
Data de nascimento (dd/mm/aaaa): ____ / ____ / ____
CPF ou outro documento de identificação na ausência do CPF
Contato do paciente (Telefone/E-mail)

4. Dados do profissional responsável pelo paciente

Nome Completo
CPF
Inscrição no Conselho Profissional-UF
Contato do profissional (Telefone/E-mail)

5. Dados do Procedimento Cirúrgico

Data da cirurgia
Nome do Hospital
CNPJ do Hospital
Município
UF

\_\_\_\_\_, \_\_\_\_ de \_\_\_\_\_, de \_\_\_\_\_

Local e data

\_\_\_\_\_

Nome do responsável técnico do detentor da anuência

\_\_\_\_\_

Nome do responsável legal do detentor da anuência