

NORMATIVE INSTRUCTION - IN No. 119, OF FEBRUARY 23, 2022

Provides for the technical attributes of medical devices selected for economic monitoring by Anvisa.

A Collegiate Board of the National Health Surveillance Agency, in use of the attribution conferred by art. 15, III and IV allied to art. 7, III and IV of Law No. 9,782, of January 26, 1999, and art. 187, VII, § 1 of the Internal Regulation approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, at a meeting held on February 23, 2022, resolves:

Art. 1 This Normative Instruction provides for the technical attributes of medical devices selected for economic monitoring by Anvisa, in accordance with the provisions of the Collegiate Board Resolution - RDC No. 478, of March 12, 2021.

Art. 2 The technical attributes of the medical devices selected for economic monitoring are included in the Annexes to this Normative Instruction.

Art. 3 Normative Instruction - IN No. 105, of October 27, is hereby revoked of 2021, published in the Federal Official Gazette No. 206, of November 3, 2021, Section 1, p. 77.

Art. 4 This Normative Instruction comes into force on April 1, 2022.

ANTONIO BARRA TORRES
CEO

ANNEX I

Set of technical attributes for medical devices registered with Anvisa as 9000027 - PHARMACOLOGICAL STENT FOR CORONARY ARTERIES or 9000030 – STENT FOR CORONARY ARTERIES

No.	ATTRIBUTE NAME TECHNICIAN	TECHNICAL ATTRIBUTE VARIATION
01	Absorption form	Permanent; Bioabsorbable.
02	Class	Pharmacological (F); Non-pharmacological; Covered (R).
03	Model	Self-expanding; Expandable by balloon.
04	platform material	Stainless steel; Cobalt chromium alloy; Platinum chromium alloy; Nickel titanium alloy; Magnesium.
05	coating of platform	Ceramics; Carbon; Other types of coating; No coating.
06	pharmacological agente	Everolimus; Sirolimus; Biolimus; Zotarolimus; Paclitaxel.
07	mesh type	PET (polyethylene terephthalate); PTFE (polytetrafluoroethylene); Polyurethane; No mesh.
08	Diameter	Open field for the variations that exist in the market. The field must contain the unit "millimeters - mm" as standard and minimum and maximum limits
09	Length	Open field for the variations that exist in the market.

		The field must contain the unit "millimeters - mm" as standard and minimum and maximum limits
10	polymer type drug eluting	Durable (permanent); Bioabsorbable; Polymer free.
11	Format	Dedicated to the fork; Not dedicated to the fork.
12	Agent distribution pharmacological	Conformal; Abluminal.
13	stem thickness	Open field for the variations that exist in the market. The field must include the unit "micrometers - µm" as standard and minimum and maximum limits
14	Polymer thickness coating	Open field for the variations that exist in the market. The field must include the unit "micrometers - µm" as standard and minimum and maximum limits
15	Polymer absorption time coating	Permanent; Open field for the variations that exist in the market. The field should contain the unit "months" and minimum and maximum limits by default.
16	Pharmacological agent elution time	Open field for the variations that exist in the market. The field should contain the unit "months" and minimum and maximum limits by default.

ANNEX II

Set of technical attributes for medical devices registered with Anvisa as
9000051 - IMPLANTABLE CARDIAC PACEMAKER WITH DOUBLE CHAMBER, WITH FREQUENCY RESPONSE; 9000052 - IMPLANTABLE CARDIAC PACEMAKER FOR DOUBLE CHAMBER, ON DEMAND; 9000053 - IMPLANTABLE SINGLE CHAMBER FIXED RATE AND DEMAND CARDIAC PACEMAKER; 9000054 - SINGLE CHAMBER IMPLANTABLE CARDIAC PACEMAKER WITH RESPONSE OF FREQUENCY; 9000055 - IMPLANTABLE PACEMAKER FOR CARDIAC RESYNCHRONIZATION THERAPY; or 9000056 - INTRACARDIAC PACEMAKER

No.	TECHNICAL ATTRIBUTE NAME	TECHNICAL ATTRIBUTE VARIATION
01	carcass material	Titanium; Stainless steel; Gold; Other
02	Connection block material	Epoxy resin; Silicone rubber.
03	battery material	Lithium; SVO (silver vanadium oxide); Other.
04	pacemaker volume	Open field.
05	Weight	Open field.
06	Dimensions	Open field.
07	Format	Curvilinear anatomy; Rectilinear.
08	implant site	Epicardial; Transvenous; Intracardiac.
09	Implant site laterality	Right; Left.
10	Therapeutic indications	Treatment of bradyarrhythmia; Treatment of chronic heart failure (CHF).
11	stimulated chamber	Right atrium; Right ventricle; Left ventricle; Right atrium + Right ventricle; Right atrium + Right ventricle + Left ventricle.
12	electrocardiogram storage	Yes; No.
13	Intracardiac electrocardiogram (IEGM) recording	Filtered; Unfiltered; Wired; Wireless.
14	heart rate sensor	Accelerometer; Physiological; Other.
15	sound alerts	Yes; No.

16	end of battery warning	Sound; Vibratory; Telemetric.
17	Radiological Identification	Yes; No.
18	Compatibility with Magnetic Resonance Imaging (MRI)	Yes, 1.5 T without restriction on body area and exposure time; Yes, 3 T without restriction of body area and exposure time; Yes, 1.5 T with body area and exposure time restriction; Yes, 3 T with body area restriction and exposure time; Yes, 1.5T with body area restriction; Yes, 3 T with body area restriction; Yes, 1.5 T with exposure time restriction; Yes, 3 T with exposure time restriction; No.
19	Projected lifetime (ISO 14708-2)1	Up to 4 years; Up to 6 years; Up to 8 years; Up to 12 years; Up to 16 years old; Up to 20 years.
20	Generator warranty period1	Up to 5 years; Between 5 and 10 years; Above 10 years.
21	Pacemaker programming mode depending on the number of chambers	Unicameral; Bicameral; Tricameral.
22	Wireless communication with programmer	Yes; No.
23	Cable-electrode connection type	IS-1; IS4; Not applicable
24	remote patient monitoring	Yes; No.
25	stimulation mode	DDDR (atrioventricular pacing; atrioventricular sensing; triggers or inhibits MP in response to stimuli; with heart rate response); VVIR (ventricular pacing; ventricular sensing; inhibits PM in response to stimuli; with heart rate response); AAIR (atrial pacing; atrial sensing; inhibits PM in response to stimuli; with heart rate response); DDIR (atrioventricular pacing; atrioventricular sensing; inhibits PM in response to stimuli; with heart rate response); AOO (atrial pacing; no chamber detected; no response to stimuli); DDD (atrioventricular pacing; atrioventricular sensing; triggers or inhibits PM in response to stimuli); DDI (atrioventricular pacing; atrioventricular sensing; inhibits MP in response to stimuli); VVI (ventricular pacing; ventricular sensing; inhibits MP in response to stimuli); AAI (atrial pacing; atrial sensing; inhibits PM in response to stimuli); AOOR (atrial pacing; no chamber detected; no response to stimuli; with heart rate response); VDD (ventricular pacing; atrioventricular sensing; triggers or inhibits PM in response to stimuli); VVT (ventricular pacing; ventricular sensing; triggers PM in response to stimuli); AAT (atrial pacing; atrial sensing; triggers PM in response to stimuli); VDI (ventricular pacing; atrioventricular sensing; inhibits PM in response to stimuli); VOO (ventricular pacing;

		no chamber detected; no response to stimuli); VDDR (ventricular pacing; atrioventricular sensing; triggers or inhibits MP in response to stimuli; with heart rate response); VDIR (ventricular pacing; detection atrioventricular; inhibits MP in response to stimuli; with heart rate response); VOOR (ventricular pacing; no chamber detected; no response to stimuli; with heart rate response); DDD-ADI (atrioventricular pacing; atrioventricular sensing; triggers or inhibits PM in response to stimuli - Atrial triggering; sensing atrioventricular; inhibits MP in response to stimuli); DVI (atrioventricular pacing; ventricular sensing; inhibits MP in response to stimuli); DOO (atrioventricular pacing; no chamber detected; no response to stimuli); DDDR-ADIR (atrioventricular pacing; atrioventricular sensing; triggers or inhibits MP in response to stimuli; with heart rate response - Atrial triggering; atrioventricular sensing; inhibits MP in response to stimuli; with heart rate response); DVIR (atrioventricular pacing; ventricular sensing; inhibits MP in response to stimuli; with heart rate response); DOOR (atrioventricular pacing; no chamber detected; no response to stimuli; with heart rate response); DDT (atrioventricular pacing; atrioventricular sensing; triggers PM in response to stimuli); OFF (turned off).
26	Polarity	Unipolar; Bipolar; Extended bipolar.
27	Atrial therapy management	Preferential atrial pacing; Atrial stabilization rate; Conducted response to atrial fibrillation; Antitachycardia stimulation; Mode change.
28	Automatic stimulation and detection	Atrial capture control; Ventricular capture control; Adaptive AV Delay; Self-adjusting sensitivity; Autocapture; Auto capture, ST segment diagnostics; Sensitivity, frequency, amplitude; Automatic threshold management.
29	Basic Frequency (Rest)	Numeric open field.
30	Decreased ventricular pacing	Mode change; AV interval extension algorithm; AV Interval; Frequency hysteresis.
31	frequency modulation	Mechanic; Physiological.
32	Management of Neurocardiogenic Syndrome	Yes; No.
33	Setting Pace and Sense	Unipolar; Bipolar; Off.
34	Polarity change for safety	Yes; No.
35	MRI parameters	Stimulation mode; Stimulation frequency; Automatic MR detection; Return timing.
36	Histograms and counters	Frequency histograms; Histogram of AV intervals; Stimulation counters; AV detection

		and conduction.
37	Diagnosis and monitoring of heart failure	Yes; No.
38	Diagnosis and monitoring of atrial arrhythmias	Atrial arrhythmia burden; Register of mode changes; Ventricular rate during atrial arrhythmia.
39	Arrhythmia LogBook/EGM	Records of atrial and ventricular arrhythmias; Algorithm records.
40	daily trends	Sensitivity tests; Impedance; Stimulation threshold; Battery longevity.
41	Telemetry	Telemetry with interrogation antenna; Router telemetry.
42	Safety mode	Yes; No.
43	electrocautery mode	Yes; No.
44	Real-time logging and recording	Yes; No.

¹For these technical attributes, based on the collected data, Anvisa it will be able to adapt the stratification of the variation, in order to guarantee the quality of the information and avoid the individualization of the medical devices.

ANNEX III

Set of technical attributes for medical devices registered with Anvisa as - 9000007 - DUAL CHAMBER IMPLANTABLE DEFIBRILLATOR; 9000008 - SINGLE CHAMBER IMPLANTABLE DEFIBRILLATOR; or 9000009 – DEFIBRILLATOR IMPLANTABLE FOR CARDIAC RESYNCHRONIZATION THERAPY

No.	ATTRIBUTE NAME	VARIATION
1.	Housing lining material	Titanium; Stainless steel; Gold; Parelene.
2.	Volume	open field.
3.	Dimensions	open field.
4.	Format	Curvilinear anatomy; Rectilinear.
5.	Therapeutic indications	Treatment of tachyarrhythmias; Treatment of bradyarrhythmias; Treatment of tachyarrhythmias and chronic heart failure (CHF); Treatment of tachyarrhythmias and bradyarrhythmias.
6.	Chamber stimulated in pacemaker function	Right atrium; Left ventricle; Right ventricle; Right atrium + Right ventricle; Right atrium + Right ventricle + Left ventricle.
7.	storage of electrocardiogram	Open field.
8.	electrocardiogram recording	Filtered; Unfiltered; Wired; Wireless.
9.	Sensor for heart rate adaptation	Accelerometer; Physiological; Mixed (accelerometer + physiological).
10.	sound alerts	Yes; No.
11.	end of battery warning	Telemetry (programmer); Via Telemedicine; Sound.
12.	Compatibility with Magnetic Resonance Imaging (MRI)	Yes, 1.5 T without restriction on body area and exposure time; Yes, 3 T without restriction of body area and exposure time; Yes, 1.5 T with body area and exposure time restriction; Yes, 3 T with body area restriction and exposure time;

		Yes, 1.5T with body area restriction; Yes, 3 T with body area restriction; Yes, 1.5 T with exposure time restriction; Yes, 3 T with exposure time restriction; No.
13.	Automatic Magnetic Field Detection	Yes; No.
14.	Projected lifetime (ISO 14708-6) ¹	Up to 5 years; From 6 to 8 years old; 9 to 11 years old; 12 to 15 years old; Above 16 years.
15.	warranty period ¹	Up to 5 years; From 6 to 8 years old; 9 to 11 years old; 12 to 15 years old; Above 16 years.
16.	Wireless communication with programmer	Yes; No.
17.	remote patient monitoring	Yes; No.
18.	Types of therapies for treating cardiac tachyarrhythmias	Antitachycardia pacing therapy + defibrillation/cardioversion; Defibrillation/cardioversion only.
19.	System setup	DF-1 transvenous single-chamber ICD; DF4 transvenous single-chamber ICD; DF-1 transvenous bicameral ICD; DF4 transvenous dual-chamber ICD; CDI + DF4 Resynchronizer + IS4; ICD + DF4 Resynchronizer + IS-1; ICD + DF-1 Resynchronizer + IS4; ICD + DF-1 Resynchronizer + IS-1; subcutaneous ICD.
20.	Multiple pacing vectors in the left ventricle	Open field.
21.	Full energy shock reserve	Open field.
22.	Double pacing in the left ventricle	Yes; No.

¹For these technical attributes, based on the collected data, Anvisa it will be able to adapt the stratification of the variation, in order to guarantee the quality of the information and avoid the individualization of the medical devices.

ANNEX IV

Set of technical attributes for medical devices registered with Anvisa as 9000018 - BIOLOGICAL CARDIAC VALVE PROSTHESIS; or 9000019 – PROSTHESIS MECHANICAL HEART VALVE

No.	ATTRIBUTE NAME	VARIATION
01	Size (diameter)	open field, in millimeters.
02	anti-calcification treatment	Yes; No.
03	Valve to be replaced	Aortic; Mitral; Pulmonary; Tricuspid.
04	Leaflet material	Bovine pericardium single strip; Triple composition bovine pericardium; Porcine with septal muscle; Porcine without septal muscle; Pyrolytic carbon; Graphite; Other.
05	structure material	Chrome-cobalt metal; Titanium metal; Polymer; Pyrolytic carbon; Nitinol.
06	Coating material of the structure of the prosthetic heart valve	bovine pericardium; Polyester fabric + biological fabric; PTFE (polytetrafluoroethylene); Polyester fabric; Pyrolytic carbon; PET (polyethylene terephthalate).
07	Positioning	Intra-annular; Supra-annular.

08	Compatibility with Magnetic Resonance Imaging (MRI)	Yes, Up to 3.0 T , with exposure time limit. Yes, Up to 1.5 T, with exposure time limit; No.
09	Visibility and radiographic identification	Visible structure (stent and/or ring) and numbering; Structure (stent and/or ring) visible; With radiopaque markers; Visible leaflet; No.
10	implant procedure	Conventional surgery; MIS surgery (ministernotomy/minithoracotomy); Percutaneous.
11	Profile of mechanical heart valve prosthesis	High; Low.
12	Possibility of ViV (Valve in Valve) procedure in biological heart valve prostheses	Yes; No.
13	storage type	In glutaraldehyde solution; In formaldehyde solution; Dry.
14	Construction of the heart valve prosthesis	Internal; External.
15	Ring expansion zone of biological prosthetic heart valves	Gift; Absent.
16	Retraction of commissural posts of biological heart valve prostheses	Yes; No.
17	True internal orifice área	Open field, in millimeters.
18	Thickness of the suture ring of biological heart valve prostheses	Open field, in millimeters.
19	Suture markings of biological heart valve prostheses	Gifts; Absent.
20	suture ring material	Polyester; PTFE (polytetrafluoroethylene); Other.
21	No. Rapid delivery system for biological heart valve prostheses	Yes; No.
22	Expansion mode of biological heart valve prostheses	Integrated balloon catheter; Independent balloon catheter; Self expanding.
23	Fixation material for biological heart valve prostheses (Fast Implant)	Stainless steel + biocompatible fabric; Nitinol.
24	Sound when opening and closing leaflets in mechanical heart valve prostheses	Yes; No.
25	Compartment axis of mechanical heart valve prostheses	Rotatable; Not rotatable.
26	Characteristics of pivot guards for mechanical valve prostheses	Open; Closed.
27	Cleaning the pivot guards of mechanical valve prostheses	Active; Passive.
28	Type	Biological; Mechanics; Transcatheter Biology.
29	Number of leaflets	1 leaflet; 2 leaflets; 3 leaflets.
30	Anticoagulation treatment in mechanical heart valve prostheses	Yes; No.