



Ministerio de Salud
Secretaria de Calidad en Salud
A.N.M.A.T.

DECLARACIÓN DE CONFORMIDAD DE MODIFICACIÓN – PM CLASE III - IV

Número de revisión: 584-56#0001

Nombre Descriptivo del producto:

Catéter Balón para angioplastia coronaria transluminal percutánea (ACTP)

Marca:

BIOSENSORS INTERNATIONAL™

Número de PM:

584-56

Disposición Autorizante o reválida: 34/21

Expediente de Autorización original: 1-47-3110-5695-20-8

MODIFICACIONES SOLICITADAS

DATO A MODIFICAR	DATOS AUTORIZADOS	MODIFICACION/RECTIFICACION AUTORIZADA
Vida útil para productos de origen importado	24 meses	24 meses (RISE NC) 36 meses (RISE SC)

**CUMPLIMIENTO DE REQUISITOS ESENCIALES DE SEGURIDAD Y DESEMPEÑO.
DISPOSICIÓN ANMAT N° 11467/24 Y GESTIÓN DE RIESGO**

ENSAYO/VALIDACION/GESTION DE RIESGO	LABORATORIO/N° DE PROTOCOLO	FECHA DE EMISIÓN
6. 6.1.1 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes EN 62366-1:2015/A1:2020 / IEC 62366-1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices MEDDEV 2.7/1 rev.4: 2016: Clinical evaluation: Guide for manufacturers and notified bodies 6.1.2 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes 6.1.3 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 10555-1:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters – Part 4: Balloon Dilatation Catheters EN ISO 25539-2:2020: Cardiovascular implants - Endovascular devices – Part 2: Vascular stents (partial for delivery system only) EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer EN ISO 15223-1:2021 Medical Devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements EN 62366-1:2015/A1:2020 / IEC 62366-1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices MEDDEV 2.7/1 rev.4: 2016: Clinical evaluation: Guide for manufacturers and notified bodies	N/A	N/A

6.1.5 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 10555-1:2023 Intravascular Catheters – Sterile and Single-use Catheters– Part1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 4: Balloon Dilatation Catheters EN ISO 25539-2:2020: Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (partial for delivery system only) EN 62366-1:2015/A1:2020 / IEC 62366- 1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer 6.1.6 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 10555-1:2023 Intravascular Catheters – Sterile and Single-use Catheters – Part 1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 4: Balloon Dilatation Catheters EN ISO 25539-2:2020: Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (partial for delivery system only) EN ISO 11607-1:2020 +A11:2022: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-2:2020+A11:2022: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes 6.1.7 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes EN ISO 10555-1:2023 Intravascular Catheters – Sterile and Single-use Catheters – Part 1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 4: Balloon Dilatation Catheters EN ISO 25539-2:2020: Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (partial for delivery system only) EN ISO 11607-1:2020 +A11:2022: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-2:2020+A11:2022: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer EN ISO 15223-1:2021 Medical Devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements		
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6.1.8 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes EN ISO 10555-1:2023 Intravascular Catheters – Sterile and Single-use Catheters – Part 1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 4: Balloon Dilatation Catheters EN ISO 25539-2:2020: Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (partial for delivery system only) EN ISO 11607-1:2020 +A11:2022: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-2:2020+A11:2022: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer EN ISO 15223-1:2021 Medical Devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements 6.1.9 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN 62366-1:2015/A1:2020 / IEC 62366- 1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices MEDDEV 2.7/1 rev.4: 2016: Clinical evaluation: Guide for manufacturers and notified bodies		
6.2 6.2.1 N/A 6.2.2 N/A	N/A	N/A
6.3 6.3.1 EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitization EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials EN ISO 10993-18:2020+A1:2023: Biological evaluation of medical devices - Part 18: Chemical characterization of materials EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes	N/A	N/A

6.3.2 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitization EN ISO 10993-18:2020+A1:2023: Biological evaluation of medical devices - Part 18: Chemical characterization of materials 6.3.3 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes EN ISO 10555-1:2023 Intravascular Catheters — Sterile and Single-use Catheters — Part 1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 4: Balloon Dilatation Catheters EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process 6.3.4 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes EN ISO 10555-1:2023 Intravascular Catheters — Sterile and Single-use Catheters — Part 1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 4: Balloon Dilatation Catheters EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process 6.3.5 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitization EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials EN ISO 10993-18:2020+A1:2023: Biological evaluation of medical devices - Part 18: Chemical characterization of materials EN ISO 10555-1:2023 Intravascular Catheters — Sterile and		
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Single-use Catheters — Part 1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters- Part 4: Balloon Dilatation Catheters EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes		
6.4 6.4.1 N/A 6.4.3 EN ISO 14971:2019 +A11:2021 Application of risk management to medical devices EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems -Requirements for regulatory purposes EN ISO 11607-1:2020 +A11:2022: Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-2:2020+A11:2022: Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes EN ISO 10555-1:2023 Intravascular Catheters — Sterile and Single-use Catheters — Part 1: General Requirements EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 4: Balloon Dilatation Catheters EN ISO 25539-2:2020: Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (partial for delivery system only) EN 62366-1:2015/A1:2020 / IEC 62366- 1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices 6.4.4 EN ISO 11135:2014+A1:2019 Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices EN 556-1:2001/AC:2006 Sterilization Of Medical Devices - Requirements For Medical Devices To Be Designated “Sterile” - Part 1: Requirements For Terminally Sterilized Medical Devices EN ISO 11737-1:2018 +A1: 2021 Sterilization of medical devices – Microbiological methods - Part 1: Determination of a population of microorganisms on products EN ISO 11737-2:2020 Sterilization of medical devices – Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process EN ISO 11607-1:2020 +A11:2022: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-2:2020+A11:2022: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes EN ISO 13485:2016+A11:2021 Medical Devices – Quality Management Systems – Requirements for regulatory purposes 6.4.5 EN ISO 13485:2016+A11:2021 Medical Devices – Quality	N/A	N/A

Management Systems – Requirements for regulatory purposes EN ISO 14644-1:2015: Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness EN ISO 14644-2:2015: Clean rooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with EN ISO 14644-1 EN ISO 14644-3:2019: Clean rooms and associated controlled environments – Part 3: Test methods EN ISO 14644-4:2022: Clean rooms and associated controlled environments – Part 4: Design, construction and start-up EN ISO 14644-5:2004: Clean rooms and associated controlled environments – Part 5: Operations EN ISO 14644-6:2007: Clean rooms and associated controlled environments – Part 6: Vocabulary EN ISO 14644-7:2004: Clean rooms and associated controlled environments – Part 7: Separative devices (clean air hoods, glove boxes, isolators and mini-environments) EN ISO 14644-8:2022: Clean rooms and associated controlled environments – Part 8: Classification of airborne molecular contamination EN 17141: 2020 Cleanrooms and associated controlled environments. Biocontamination control 6.4.6 N/A 6.4.7 N/A		
6.5 6.5.1 EN ISO 14971:2019 +A11:2021 Medical Devices – Application of Risk Management to Medical Devices EN 62366-1:2015/A1:2020 / IEC 62366- 1:2015+A1:2020 Medical devices –Application of usability engineering to medical devices EN ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications EN ISO 10555-1:2023 Intravascular Catheters — Sterile and Single-use Catheters — Part 1: General Requirements EN ISO 20417:2021 Medical devices – Information to be supplied by the manufacturer EN ISO 15223-1:2021 Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements 6.5.2 EN ISO 14971:2019 +A11:2021 Medical Devices – Application of Risk Management to Medical Devices EN ISO 13485:2016+A11:2021 Medical Devices – Quality Management Systems – Requirements for regulatory purposes EN 62366-1:2015/A1:2020 / IEC 62366- 1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices	N/A	N/A

EN ISO 10555-1:2023 Intravascular Catheters — Sterile and Single-use Catheters — Part 1: General Requirements EN ISO 10555-4:2023 (Appendix D): Intravascular Catheters – Sterile and Single-use Catheters – Part 4: Balloon Dilatation Catheters 6.5.3 N/A 6.5.4 N/A 6.5.5 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN 62366-1:2015/A1:2020 / IEC 62366- 1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices EN ISO 10555-1:2023 Intravascular Catheters — Sterile and Single-use Catheters — Part 1: General Requirements EN ISO 25539-2:2020: Cardiovascular implants -- Endovascular devices -- Part 2: Vascular stents (partial for delivery system only) EN ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications 6.5.6 EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer EN ISO 15223-1:2021 Medical Devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements 6.5.7 N/A 6.5.8 EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer		
6.6 N/A	N/A	N/A
6.7 N/A	N/A	N/A
6.8 N/A	N/A	N/A
6.9 N/A	N/A	N/A
6.10 6.10.1 EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer EN ISO 15223-1:2021 Medical Devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	N/A	N/A
6.11 N/A	N/A	N/A
6.12 N/A	N/A	N/A
6.13 N/A	N/A	N/A
7. 7.1 7.1.1	N/A	N/A

EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process		
EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood		
EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity		
EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitization		
EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity		
EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials		
EN ISO 10993-18:2020+A1:2023: Biological evaluation of medical devices - Part 18: Chemical characterization of materials		
EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes 7.1.2		
EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices		
EN ISO 13485:2016+A11:2021 Medical Devices - Quality Management Systems - Requirements for regulatory purposes		
EN ISO 10555-1:2023 Intravascular Catheters — Sterile and Single-use Catheters — Part 1: General Requirements		
EN ISO 10555-4:2023 Intravascular Catheters – Sterile and Single-use Catheters - Part 4: Balloon Dilatation Catheters		
EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process 7.1.3		
EN ISO 14971:2019 +A11:2021 Medical Devices - Application of Risk Management to Medical Devices		
7.2 N/A 7.3 N/A 7.4 N/A 7.5 N/A	N/A	N/A

8. N/A	N/A	N/A
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El responsable legal y su responsable técnico en nombre y representación de la firma TECNOLOGY S.R.L., declaran bajo juramento lo antes declarado y son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento mantener en su establecimiento y a disposición de la autoridad sanitaria la documentación allí declarada y la que establece la Disposición ANMAT N° 64/25 y la Disposición 9688/19, bajo apercibimiento de lo que establece la Ley N° 16.463, el Decreto N° 341/92 y las que correspondan del Código Penal en caso de falsedad.

En caso de inexactitud o falsedad de la información o documentación, la Administración Nacional podrá suspender, cancelar, prohibir la comercialización y solicitar retiro del mercado de lo ya autorizado e iniciar los sumarios que pudieran corresponder.



RODRIGUEZ Susana Del Valle
CUIL 27134650341

Firma del Responsable Técnico



LUSARDI Fernando Cristian
CUIL 20149784773

Firma del Representante Legal



BALDONEDO Sabrina Laura
CUIL 27263872563

Habiéndose cumplimentado con lo previsto en la Disposición ANMAT N° 9688/19, se autoriza las modificaciones solicitadas.

LUGAR Y FECHA: Argentina, 19 agosto 2025



BODNAR Andrea Veronica
CUIL 27254978472

Dirección de Evaluación de Registro de
Productos Médicos ANMAT
Firma y Sello



TERRIZZANO Maria Lorena
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Instituto Nacional de Productos Médicos de
Productos Médicos ANMAT
Firma y Sello



La validez del presente documento deberá verificarse mediante el código QR.

Tramitada por Expediente N°: 1-0047-3110-005531-25-1



ABRIOLA Leticia Adriana
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