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

ANEXO II

DECLARACIÓN DE CONFORMIDAD DE MODIFICACIÓN – PM CLASE I- II

Número de revisión: 1311-53#0002

Fecha de Emisión de la Declaración revisión 00-Disposición Autorizante o su reválida: 19/09/2024

Número de PM:

1311-53

Nombre Descriptivo del producto:

Sistemas oftalmológicos de tomografía de coherencia óptica

Código de identificación y nombre técnico UMDNS:

18-191 Sistemas de Exploración, por Láser, Tomografía Óptica Coherente, Oftálmicos

Clase de Riesgo:
Clase II

Marca de (los) producto(s) médico(s):

TowardPi

Modelos (en caso de clase II y equipos):

BM-400K Ultra, BM-400K MAX, BM-400K NF, BM-400K, BM Lite, YG-250K Ultra, YG-250K NF, YG-100K Ultra, YG-100K NF, YG-100K MAX, YG-100K PRO, YG Lite

Composición cuali-cuanti porcentual exacta (si corresponde):

-

Indicación/es autorizada/s:

El sistema es un sistema de tomografía de coherencia óptica oftálmica, destinado a la obtención de imágenes transversales y tridimensionales in vivo y a la medición del tejido ocular, así como a la visualización no invasiva de la vasculatura ocular basada en angiografía por OCT (OCTA).

Período de vida útil (si corresponde):

8 años

Método de Esterilización (si corresponde):

-

Forma de presentación:

Envase conteniendo una (1) unidad

Condición de uso:

Uso exclusivo a profesionales e instituciones sanitarias

Nombre del fabricante:

Toward Pi (Shanghai) Medical Technology Ltd.

Lugar/es de elaboración:
Room 261, Building 147, No. 500, Zhennan Road, Putuo District, 200331, Shanghai, China

En nombre y representación de la firma Omni S.R.L. , el responsable legal y el responsable técnico declaran bajo juramento que los productos médicos enumerados en el presente Anexo, satisfacen los Requisitos Esenciales de Seguridad y Desempeño de Productos Médicos por la Disposición ANMAT N° 11467/24, que cumplen y se encuentra a disposición de la Autoridad Sanitaria la documentación técnica que contenga los requerimientos solicitados en el Apéndice IV y V del Anexo del Reglamento Técnico aprobado por Disposición ANMAT N° 64/25 y Disposición ANMAT Nº 9688/19.

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
• ISO 14971:2019 • ISO/TR 24971:2020 • MDCG 2020-5 • MEDDEV 2.7/1 rev.4 • MDCG 2020-7 • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • EN 60601-1-2:2015+A1:2021/ IEC 60601-1-2:2014+AMD1:2020 • IEC 60825-1: 2014	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF06-009 Clinical Evaluation Report B/0 • E551795-D6001-IT-1 • 4792043841.2.1-1 EMC Test Report • 2026-JK-0020 IEC 60825 test report	-
6.1.1. • ISO 14971:2019 • ISO / TR 24971:2020	• TOPI-21002-YF01-004 Risk Management Plan A/1 • TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF06-011 Risk Management Matrix of Ophthalmic Optical Coherence Tomography Systems A/2	-
6.1.2. • ISO 14971:2019 • ISO/TR 24971:2020 • MDCG 2020-8 • MDCG 2019-9	• TOPI-21002-YF01-004 Risk Management Plan A/1 • TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF06-011 Risk Management Matrix of Ophthalmic Optical Coherence Tomography System A/2 • TOP	-
6.1.3. / 6.1.4. • ISO 14971:2019 • ISO/TR 24971:2020 • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmi	-
6.1.5. • ISO 14971:2019 • ISO/TR 24971:2020 • EN ISO 20417:2021/ ISO 20417:2021 • EN 62366-1:2015 / A1: 2020 / A1: 2020 • EN 60601-1-6 :2010 / A1:2015	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmi	-
6.1.6. • ISO 14971:2019 • ISO/TR 24971:2020 • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmi	-
6.1.7. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-034 Lifetime Evaluation Report A/1 • TOPI-21002-	-

• EN ISO 15223-1:2016 • EN ISO 780:2015 • ASTM D 4169-2016	YF03-032 Packaging verification Report A/1 • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography System	
6.1.9. • ISO 14971:2019 • ISO/TR 24971:2020 • MEDDEV 2.7/1 rev.4 • MDCG 2020-5 • MDCG 2020-7	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF06-011 Risk Management Matrix of Ophthalmic Optical Coherence Tomography System A/2 • TOPI-21002-YF06-009 Clinical evaluation report B/0	-
6.3.1. • ISO 10993-1:2018 • ISO 10993-5: 2009 • ISO 10993-10:2021 • ISO 10993-23:2021 • ISO 15004-2:2007 • Regulation (EC) No 1907/2006	• TOPI-21002-YF03-029 Product System Verification Plan A/1 • TOPI-21002-YF05-002 Product System Verification Report A/1 • TOPI-21002-YF05-005 Biocompatibility Evaluation Report B/0 • TOPI-21002-YF06-0	-
6.3.2. • ISO 14971:2019 • ISO/TR 24971:2020 • ASTM D 4169-2016	• TOPI-21002-YF03-032 Packaging verification Report A/1 • TOPI-21002-YF06-011 Risk Management Matrix of Ophthalmic Optical Coherence Tomography System A/2 • TOPI-21002-YF06-005 Risk Management Report	-
6.3.4. • ISO 14971:2019 • ISO/TR 24971:2020	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF05-003 Transport testing Protocol A/1 • TOPI-21002-YF05-004 Transport testing Report A/1 • TOPI-21002-YF03-032 Packaging verification Re	-
6.3.5. • ISO 14971:2019 • ISO/TR 24971:2020 • EN ISO 20417:2021/ ISO 20417:2021 • EN 62366-1:2015 / A1: 2020 • EN 60601-1-6:2010/A1:2015	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmi	-
6.4.1. • EN ISO 20417:2021/ ISO 20417:2021 • ISO 14971:2019 • ISO/TR 24971:2020	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.4.6. • ASTM D 4169-2016	• TOPI-21002-YF03-032 Packaging verification Report A/1 • TOPI-21002-YF03-031 Packaging verification Protocol A/1	-
6.4.7.	• TOPI-21002-LI-010, TOPI-21002-LI-	-

• EN ISO 15223-1:2021	017 label of Ophthalmic Optical Coherence Tomography Systems. • TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-	
6.5.2. • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1: 2014 • EN 60601-1-2:2015+A1:2021/ IEC 60601-1-2:2014+AMD1:2020 • EN 62366-1:2015/A1:2020 • EN 60601-1-6:2010/ A1:2015 • MDCG 2019-16	• TOPI-21002-YF06-005 Risk Management Report A/2 • E551795-D6001-IT-1 • 4792043841.2.1-1-1 EMC Test Report • 2026-JK-0020 IEC 60825 test report • TOPI-21002-YF02-007 Usability Design Specifications A/	-
6.5.3. • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1: 2014	• E551795-D6001-IT-1 • 2026-JK-0020 IEC 60825 test report	-
6.5.4. • EN ISO 20417: 2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.5.5. • EN ISO 20417: 2021/ ISO 20417:2021 • EN 60601-1-2: 2015 / A1:2021/ IEC 60601-1-2:2014/ AMD1:2020	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.5.7. • EN 62366-1:2015/ A1:2020:2015 • EN 60601-1-6: 2010/ A2:2021	• TOPI-21002-YF02-007 Usability Design Specifications A/1	-
6.5.8. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.9.1. • ISO 16971:2015	• TOPI-21002-YF03-044 Product Performance Verification protocol A/1 • TOPI-21002-YF03-045 Product Performance Verification Report A/1 • TOPI-21002-YF06-016 Ophthalmic instruments — Optical coherence t	-
6.9.1.	• TOPI-21002-YF03-044 Product	-

• ISO 16971:2015 • ISO 15004-1:2020 • ISO 15004-2:2007	Performance Verification protocol A/1 • TOPI-21002-YF03-045 Product Performance Verification Report A/1 • TOPI-21002-YF06-020 The Checklist of ISO15004-2 • TOPI-21002-YF0	
6.8.1. • EN 62304:2006 /A1:2015 • ISO 14971:2019 • ISO/TR 24971:2020	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF01-003 Software Development Plan A/1	-
6.8.2. • ISO 14971:2019 • ISO/TR 24971-2020 • EN 62304:2006/A1:2015 • MDCG 2019-16	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF01-003 Software Development Plan A/1 • TOPI-21002-YF03-003 Risk analysis, control measures, and benefit/risk analysis A/2 • TOPI-21002-Y	-
6.8.4. • EN 62304:2006/A1:2015 • EN ISO 20417:2021/ ISO 20417:2021 • MDCG 2019-16	• TOPI-21002-YF03-023 Summary of Cybersecurity Conformity A/1 • TOPI-21002-YF03-003 Risk analysis, control measures, and benefit/risk analysis A/2 • TOPI-21002-YF02-008 Software Requirements Specifica	-
6.7.1. • ISO 14971:2019 • ISO/TR 24971:2020	• TOPI-21002-YF06-005 Risk Management Report A/2	-
6.7.5. • EN 60601-1-2: 2015 / A1:2021/ IEC 60601-1-2:2014/ AMD1:2020	• 4792043841.2.1-1 EMC Test Report	-
6.7.6. • EN 60601-1-2: 2015 / A1:2021/ IEC 60601-1-2:2014/ AMD1:2020	• 4792043841.2.1-1 EMC Test Report	-
6.7.7. • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1: 2014 • EN ISO 20417:2021/ ISO 20417:2021	• E551795-D6001-IT-1 • 2026-JK-0020 IEC 60825 test report • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of	-
6.5.6. • MDCG 2019-16 • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-003 Risk analysis, control measures, and benefit/risk analysis A/2 • TOPI-21002-YF02-008 Software Requirements Specification A/1 • TOPI-21002-YF01-003 Software Development Plan A/1 •	-
6.6.1 • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1: 2014	• E551795-D6001-IT-1 • 2026-JK-0020 IEC 60825 test report	-
6.6.2.	• E551795-D6001-IT-1 • 2026-JK-0020	-

• EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1: 2014	IEC 60825 test report	
6.6.3. • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1: 2014	• E551795-D6001-IT-1 • 2026-JK-0020 IEC 60825 test report	-
6.6.4. • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • •ISO 14971:2019 • ISO/TR 24971:2020	• E551795-D6001-IT-1 • TOPI-21002-YF06-011 Risk Management Matrix of Ophthalmic Optical Coherence Tomography System A/2	-
6.6.4. • ISO 14971:2019 • ISO/TR 24971:2020 • EN ISO 20417: 2021/ ISO 20417:2021 • EN ISO 15223-1:2016	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmi	-
6.6.5. • ISO 14971:2019 • ISO/TR 24971:2020 • EN ISO 20417:2021/ ISO 20417:2021 • EN ISO 15223-1:2016	• TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmi	-
7.4.1. • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1:2014/ EN 60825-1:2014+A11:2021 • ISO 15004-1:2020 • ISO 15004-2:2007	• E551795-D6001-IT-1 • 2026-JK-0020 IEC 60825 test report • TOPI-21002-YF03-045 Product Performance Verification Report A/1 A/0 • TOPI-21002-YF06-020 The Checklist of ISO15004-2	-
7.4.2. • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1:2014/ EN 60825-1:2014+A11:2021 • ISO 14971:2019 • ISO 15004-1:2020 • ISO 15004-2:2007	• E551795-D6001-IT-1 • 2026-JK-0020 IEC 60825 test report • TOPI-21002-YF06-005 Risk Management Report A/2 • TOPI-21002-YF06-020 The Checklist of ISO15004-2	-

6.9.1.c) • EN ISO 15223-1:2016 • EN ISO 20417:2021/ ISO 20417:2021 • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60825-1:2014/ EN 60825-1:2014+A11:2021	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021 • EN ISO 15223-1:2016	• TOPI-21002-YF03-054 Verification Protocol for Instructions for Use, Labels and Drawings • TOPI-21002-YF03-055 Verification Report for Instructions for Use, Labels and Drawings • TOPI-21002-YF03-079	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021 • EN ISO 15223-1:2016	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.10.1. • Regulation (EU) 2017/745 Article 27(4) • Regulation (EU) 2017/745 Part C of Annex VI	• TOPI-CX9112 Control Procedure for UDI • TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021 15223	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021 14971	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence	-

	Tomography Systems A/0 • TOPI	
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021 • EN ISO 15223-1:2016	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.10.1. • EN ISO 15223-1:2016	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	-
6.10.1. • EN ISO 15223-1:2016	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	-
6.10.1. • EN ISO 15223-1:2016	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	-
6.10.1. • EN ISO 15223-1:2016	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	-
6.10.1. • EN ISO 15223-1:2016	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	-
6.10.1. • Regulation (EU) 2017/745 Article 27(4) • Regulation (EU) 2017/745 Part C of Annex VI	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	-
6.10.1. • EN ISO 15223-1:2016	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical	-

	Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	
6.10.1. • EN ISO 15223-1:2016	• TOPI-21002-LI-010, TOPI-21002-LI-017 label of Ophthalmic Optical Coherence Tomography Systems • TOPI-21002-LI-011, TOPI-21002-LI-018 label of Ophthalmic Optical Coherence Tomography Systems-Scanner	-
6.10.1. • IEC 60825-1: 2014 • EN ISO 15223-1:2016	• TOPI-21002-LI-003 Laser Classification Marking A/0	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0	-
6.10.1. • ISO 14971:2019 • ISO/TR 24971:2020 • MEDDEV 2.7/1 rev.4 • IEC 60825-1: 2014	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.10.1. • ISO 16971:2015	• TOPI-21002-YF03-044 Product Performance Verification protocol A/1 • TOPI-21002-YF03-045 Product Performance Verification Report A/1	-
6.10.1. EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOP	-
6.10.1. • TOPI-21002-YF05-005	• STI-20230721-023S-4 In Vitro Cytotoxicity Test • STI-20230721-	-

Biocompatibility Evaluation Report • DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL • REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	023S-6 Skin Sensitization Test • STI-20230721-023S-2 Skin Irritation Test • NWD01S10002401E In Vitro Cytotoxicity Test Report • NWD01S10	
6.10.1. • EN 60601-1:2006+A1:2013+A2:2021+A13:2024/ IEC 60601-1:2005+AMD1:2012+AMD2:2020 • EN 60601-1-2:2015+A1:2021/ IEC 60601-1-2:2014+AMD1:2020 • IEC 60825-1: 2014 • ISO 15004-2:2007 • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021	• TOPI-21002-YF03-079 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0 • TOPI-21002-YF03-078 Instruction For Use of Ophthalmic Optical Coherence Tomography Systems A/0	-
6.10.1. • EN ISO 20417:2021/ ISO 20417:2021 • EN 62304:2006/A1:2015	• TOPI-21002-YF03-064 Ophthalmic Optical Coherence Tomography Systems Software Instruction Manual A/1 • TOPI-21002-YF03-027 Software Life Cycle Implementation Check Table A/1	-

El responsable legal y su responsable técnico 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 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.

LUGAR Y FECHA: Argentina, 02 julio 2026

ROMER O Isabel
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Responsable Legal
Firma y Sello

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Responsable Técnico
Firma y Sello

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

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT Nº 9688/19, quedando inscripta la modificación en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de **Omni S.R.L.** bajo el número PM **1311-53** en la Ciudad de Buenos Aires a los días 02 julio 2026
Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad, la cual mantendrá la vigencia que consta en la Declaración inicial revisión 00 o Disposición Autorizante o su reválida.

anmat
BODNAR Andrea Veronica
CUIL 27254978472

Dirección de Evaluación de Registro
Firma y Sello

Instituto Nacional de Productos Médicos
Firma y Sello

Código "N°rev legajo#version" vigente a partir de 07/02/22, reemplaza la anterior codificación.
La validez del presente documento deberá verificarse mediante el código QR.

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