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A
Apêndice

Tabela A.1: Documentos nacionais e internacionais, em ordem cronológica, importantes para a avaliação metrológica do OCT.

Organização	**Documento**	**Ano**	**Nome**
ANSI	Z136.1 ed.1.0	1973	Safe Use of Lasers
IEC	IEC 60601-1 ed1.0 (1977-01)	1977	Medical electrical equipment. Part 1: General requirements.
ABNT	Z136.2- ed.1.0	1977	Safe Use of Optical Fiber Communication Systems Utilizing Laser Diode and LED Sources
IEC	IEC 60601-1-am1 ed1.0 (1984-01)	1984	Amendment 1 - Medical electrical equipment. Part 1: General requirements.
ISO	ISO 7944:1984	1984	Optics and optical instruments – Reference wavelengths
IEC	IEC 60825-1 ed1.0 (1984)	1984	Safety of laser products - Part 1: Equipment classification and requirements
IEC	IEC 60601-1 ed2.0 (1988-12)	1988	Medical electrical equipment - Part 1: General requirements for safety
ANSI	ANSI Z136.3	1988	Safe Use of Lasers in Health Care Facilities

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
IEC	IEC 60601-1-am1 ed2.0 (1991-11)	1991	Amendment 1 - Medical electrical equipment - Part 1: General requirements for safety
IEC	IEC 60601-2-22 ed1.0 (1992-01)	1992	Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
IEC	IEC 60601-1-2 ed1.0 (1993-04)	1993	Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests
IEC	IEC 60825-2 ed1.0	1993	Safety of laser products - Part 2: Safety of optical fibre communication systems
IEC	IEC 60825-1 ed1.0 (1993-11)	1993	Safety of laser products - Part 1: Equipment classification, requirements and user's guide
ABNT	ABNT NBR IEC 60601-1:1994	1994	Equipamento eletromédico - Parte 1: Prescrições gerais para segurança
IEC	IEC 60601-1-am2 ed2.0 (1995-03)	1995	Amendment 2 - Medical electrical equipment - Part 1: General requirements for safety

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
IEC	IEC 60601-2-22 ed2.0 (1995-11)	1995	Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
IEC	IEC 60601-1-4 ed1.0 (1996-05)	1996	Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems
ISO	ISO 13485:1996	1996	Quality systems – Medical devices – Particular requirements for the application of ISO 9001
ISO	ISO 10993-12:1996	1996	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO	ISO 14155:1996	1996	Clinical investigation of medical devices
ISO	ISO 11553:1996	1996	Safety of machinery – Laser processing machines – Safety requirements
ABNT	ABNT NBR IEC 60601-2-22:1997	1997	Equipamento eletromédico - Parte 2: Prescrições particulares para a segurança de equipamento terapêutico e de diagnóstico a laser

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
ABNT	ABNT NBR IEC 60601-1-1:1997	1997	Equipamento eletromédico Parte1: Prescrições gerais para segurança - 1. Norma Colateral: Prescrições de segurança para sistemas eletromédicos
ABNT	ABNT NBR IEC 60601-1-2:1997	1997	Equipamento eletromédico Parte 1: Prescrições gerais para segurança - 2. Norma colateral: Compatibilidade eletromagnética - Prescrições e ensaios
ANSI	Z136.2	1997	Safe Use of Optical Fiber Communication Systems Utilizing Laser Diode and LED Sources
IEC	IEC 60825-1-am1 ed1.0 (1997-09)	1997	Amendment 1 - Safety of laser products - Part 1: Equipment classification, requirements and user's guide
ISO	ISO 7944:1998	1998	Optics and optical instruments – Reference wavelengths
ISO	ISO 14971-1:1998	1998	Medical devices – Risk management – Part 1: Application of risk analysis
IEC	IEC 60825-1 ed1.1 Consol. with am1 (1998)	1998	Safety of laser products - Part 1: Equipment classification, requirements and user's guide

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
IEC	IEC 60601-1-4-am1 ed1.0 (1999-10)	1999	Amendment 1 - Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems
IEC	IEC/TR 60825-9 ed1.0 (1999-10)	1999	Safety of laser products - Part 9: Compilation of maximum permissible exposure to incoherent optical radiation
IEC	IEC/TR 60825-8 ed1.0 (1999-11)	1999	Safety of laser products - Part 8: Guidelines for the safe use of medical laser equipment
ISO	ISO 14969:1999	1999	Quality systems – Medical devices – Guidance on the application of ISO 13485 and ISO 13488
IEC	IEC 60601-1-4 ed1.1 (2000-04)	2000	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
ABNT	ABNT NBR 14588(2000)	2000	Fibras ópticas – Determinação do raio de encurvamento - Método de ensaio

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
IEC	IEC 60601-1-4 ed1.1 Consol. with am1 (2000)	2000	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
ISO	ISO 14971:2000	2000	Medical devices – Application of risk management to medical devices
ANSI	Z136.1	2000	Safe use of lasers
IEC	IEC 60825-2 ed2.0 (2000-05)	2000	Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS)
IEC	IEC 60601-1-2 ed2.0 (2001-09)	2001	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
ABNT	ABNT NBR IEC 60601-2-2:2001	2001	Equipamento eletromédico -Parte 2-2: Prescrições particulares para segurança de equipamento cirúrgico de alta frequência
IEC	IEC 60825-1 ed1.2 Consol. with am1&2 (2001)	2001	Safety of laser products - Part 1: Equipment classification, requirements and user's guide
ISO	ISO 13485(2003)	2003	Medical devices – Quality management systems – Requirements for regulatory purposes

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
ISO	ISO 14155-1:2003	2003	Clinical investigation of medical devices for human subjects – Part 1: General requirements
ISO	ISO/TR 14969 (2004)	2004	Medical devices – Quality management systems – Guidance on the application of ISO 13485: 2003
ISO	ISO/TR 11146-3:2004	2004	Lasers and laser-related equipment – Test methods for laser beam widths, divergence angles and beam propagation ratios - Part 3: Intrinsic and geometrical laser beam classification, propagation and details of test methods
ISO	ISO 11252:2004	2004	Lasers and laser-related equipment – Laser device – Minimum requirements for documentation
ABNT	ABNT NBR IEC 60601-1-1(2004)	2004	Equipamento eletromédico - Parte1-1: Prescrições gerais para segurança - Norma Colateral: Prescrições de segurança para sistemas eletromédicos
ABNT	ABNT NBR IEC 60601-1-4(2004)	2004	Equipamento eletromédico - Parte 1-4: Prescrições gerais para segurança - Norma colateral: Sistemas eletromédicos programáveis

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
ABNT	ABNT NBR ISO 7944(2004)	2004	óptica e instrumentos ópticos - Comprimentos de onda de referência
IEC	IEC/TRF 60601-1-2 ed1.0 (2004-04)	2004	This Test Report Form applies to IEC 60601-1-2 : 2001 (Second Edition)
IEC	IEC 60601-1-2-am1 ed2.0 (2004-09)	2004	Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC	IEC 60601-1-2 ed2.1 Consol. with am1 (2004)	2004	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
ABNT	ABNT NBR IEC 60601-1-4:2004	2004	Equipamento eletromédico - Parte 1-4: Prescrições gerais para segurança - Norma colateral: Sistemas eletromédicos programáveis
ABNT	ABNT NBR ISO 7944:2004	2004	Óptica e instrumentos ópticos - Comprimentos de onda de referência
ABNT	ABNT NBR ISO 14155-1:2004	2004	Clinical investigation of medical devices for human subject Part 1: General requirements

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
ABNT	ABNT NBR ISO 14971:2004	2004	Produtos para a saúde - Aplicação de gerenciamento de risco em produtos para a saúde
IEC	IEC 60825-2 ed3.0 (2004-06)	2004	Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS)
IEC	IEC 60601-1 ed3.0 (2005-12)	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ISO	ISO/TR 14999-1(2005)	2005	Optics and photonics – Interferometric measurement of optical elements and optical systems – Part 1: Terms, definitions and fundamental relationships
ISO	ISO/TR 14999-2(2005)	2005	Optics and photonics – Interferometric measurement of optical elements and optical systems – Part 2: Measurement and evaluation techniques
ISO	ISO/TR 14999-3(2005)	2005	Optics and photonics – Interferometric measurement of optical elements and optical systems – Part 3: Calibration and validation of interferometric test equipment and measurements

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
IEC	IEC 60601-1-2 ed2.0 (2005-09)	2005	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC	IEC 60601-1-2-am1 ed2.0 (2005-09)	2005	Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC	IEC 60601-1-2 ed2.1 Consol. with am1 (2005)	2005	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO	ISO/TR 11146-3:2004/Cor 1:2005	2005	Corrigenda, Amendments and other parts
ANSI	ANSI Z136.3-2005	2005	Safe Use of Lasers in Health Care
ISO	ISO 11553-1:2005	2005	Safety of machinery – Laser processing machines – Part 1: General safety requirements
IEC	IEC/TR 60825-8 ed2.0 (2006-12)	2006	Safety of laser products - Part 8: Guidelines for the safe use of laser beams on humans

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
ISO	ISO 11145:2006	2006	Optics and photonics – Lasers and laser-related equipment – Vocabulary and symbols
IEC	IEC/TRF 60601-1-4 ed3.0 (2006-09)	2006	This Test Report Form applies to IEC 60601-1-4: 1996 (First Ed.) + Am.1: 1999 (Consolidated 1.1 Ed.) for use with IEC 60601-1 (1988); Amts 1 (1991) and 2 (1995)
IEC	IEC/TRF 60601-2-22 ed2.0 (2006-10)	2006	This Test Report Form applies to IEC 60601-2-22:1995 (Second Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995
ISO	ISO/TS 20993:2006	2006	Biological evaluation of medical devices – Guidance on a risk-management process
IEC	IEC 60601-2-22 ed3.0 (2007-05)	2007	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
ISO	ISO 14971:2007	2007	Medical devices – Application of risk management to medical devices

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
ISO	IEC 62366(2007)	2007	Medical devices – Application of usability engineering to medical devices
IEC	IEC 60825-1 ed2.0 (2007-03)	2007	Safety of laser products - Part 1: Equipment classification and requirements
IEC	IEC 62366 ed1.0 (2007-10)	2007	Medical devices - Application of usability engineering to medical devices
IEC	IEC 60601-1-2 ed3.0 (2007-03)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO	ISO 10993-12:2007	2007	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ANSI	ANSI Z136.1-2007	2007	American National Standard for Safe Use of Lasers
IEC	IEC 60825-2 ed3.1 Consol. with am1 (2007)	2007	Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS)
ISO	ISO 11553-2:2007	2007	Safety of machinery – Laser processing machines – Part 2: Safety requirements for hand-held laser processing devices

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
IEC	IEC/TRF 62366 ed1.0 (2008-07)	2008	This Test Report Form applies to IEC 62366:2007(ed.1)
IEC	IEC/TR 61258 ed2.0 (2008-08)	2008	Guidelines for the development and use of medical electrical equipment educational materials
IEC	IEC/TRF 60601-1-2 ed2.0 (2008-06)	2008	This Test Report Form applies to IEC 60601-1-2: 2007 (Third Edition)
IEC	ISO 10993-1 (2009)	2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC	IEC/TRF 60601-1-2 ed3.0 (2009-06)	2009	This Test Report Form applies to IEC 60601-1-2: 2001 (Second edition) + A1 for use with IEC 60601-1: 1988 (Second edition) + A1 + A2
ISO	ISO 13485:2003/Cor 1:2009	2009	Corrigenda, Amendments and other parts
ISO	SO 7944:1998/Cor 1:2009	2009	Corrigenda, Amendments and other parts
ISO	ISO 10993-1:2009	2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ABNT	ABNT NBR ISO 14971:2009	2009	Produtos para a saúde - Aplicação de gerenciamento de risco a produtos para a saúde

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
IEC	IEC 60601-1-6 ed3.0 (2010-01)	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ABNT	ABNT NBR IEC 60601-1:2010	2010	Equipamento eletromédico - Parte 1: Requisitos gerais para segurança básica e desempenho essencial
ABNT	ABNT NBR IEC 60601-1-2:2010	2010	Equipamento eletromédico -Parte 1-2: Requisitos gerais para segurança básica e desempenho essencial - Norma colateral: Compatibilidade eletromagnética - Requisitos e ensaio
IEC	IEC 60825-2 ed3.2 Consol. with am1&2 (2010)	2010	Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS)
IEC	IEC 60601-2-57 (2011)	2011	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment
IEC	IEC/TRF 62366 ed2.0 (2011-07)	2011	This Test Report Form applies to IEC 62366: 2007 (First Edition) for use in conjunction with IEC 60601-1-6: 2010

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Tabela A.1 – Continuação

Organização	**Documento**	**Ano**	**Nome**
IEC	IEC/TRF 60601-1-2 ed4.0 (2011-06)	2011	This Test Report Form applies to IEC 60601-1-2: 2007 (Third Edition)
ABNT	ABNT NBR ISO 7944:2011	2011	Óptica e instrumentos ópticos - Comprimentos de onda de referência
ISO	ISO 14155:2011	2011	Clinical investigation of medical devices for human subjects – Good clinical practice
ISO	ISO 14155:2011/Cor 1:2011	2011	Corrigenda, Amendments and other parts
ANSI	ANSI Z136.3-2011	2011	Safe Use of Lasers in Health Care
IEC	IEC/TRF 60601-2-22 ed3.0 (2012-03)	2012	This Test Report Form applies to IEC 60601-2-22: 2007 (Third Edition) for use in conjunction with IEC 60601-1: 2005 (Third Edition)