MEDICAL DEVICES PRODUCT STANDARDS (HARMONISATION STATUS)

- **MEDICAL DEVICES**

LEGEND

REG	Standards used in regulations
GOV	Standards used in government procurement
DIR	Direct use without adoption of the international standard as a national standard and no conflicting national standard
IDT / Ed. X	Identical adoption of the international standard / Edition no. of the international standard adopted
MOD / Ed. X	Modified adoption of the international standard / Edition no. of the international standard adopted

MEDICAL DEVICES

FIRST PRIORITY

NO.	TITLE OF STANDARDS	REFERENCES	STATUS OF ADOPTION AND VERSION OF INTERNATIONAL STANDARDS ADOPTED									
			BN	KH	ID	LA	MY	MM	PH	SG	TH	VN
1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	IEC 60601-1:2005 Third edition	Direct use	Direct use	Identical adoption No SNI number yet	Direct use	MS IEC 60601-1:2006	Direct use	**IDT**	Direct use	IDT	**TCVN 7303-1: 2009**
2	Conformity assessment- General requirements for accreditation bodies accrediting conformity assessment bodies	ISO/IEC 17011	Direct use	Direct use	Direct use	Direct use	MS ISO/IEC 17011:2005	Direct use	**IDT**	Direct use	IDT (TIS 17011-2548)	**TCVN ISO/IEC 17011:2007**
3	Medical devices -- Quality management systems -- Requirements for regulatory purposes	ISO 13485:2003	Direct use	Direct use	National GMP	Direct use	MS ISO 13485:2006	Direct use	**IDT**	Direct use	IDT (TIS 13485-2547)	**TCVN ISO 13485: 2004**

NO.	TITLE OF STANDARDS	REFERENCES	STATUS OF ADOPTION AND VERSION OF INTERNATIONAL STANDARDS ADOPTED									
			BN	KH	ID	LA	MY	MM	PH	SG	TH	VN
4	Medical devices -- Quality management systems -- Guidance on the application of ISO 13485: 2003	ISO/TR 14969:2004	Direct use	Direct use	National GMP	Direct use	MS 1961:2007 (ISO/TR 14969:2004 , IDT)	Direct use	**IDT**	Direct use	Direct use	**TCVN 8331: 2010**
5	Medical devices -- Application of risk management to medical devices	ISO 14971:2007	Direct use	Direct use	Direct use	Direct use	MS ISO 14971:2009	Direct use	**Direct use**	Direct use	Direct use	**TCVN 8023: 2009**
6	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	ISO 15223-1:2007	Direct use	Direct use	Direct use	Direct use	MS ISO 15223-1:2009	Direct use	**Direct use**	Direct use	IDT (ISO15223-1:2012,in the process of adoption)	**TCVN 6196-1: 2008**
7	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	ISO 11135-1:2007	Direct use	Direct use	Direct use	Direct use	MS ISO 11135-1: 2010	Direct use	**Direct use**	Direct use	IDT	**TCVN 7392 : 2004**
8	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	ISO 11137-1:2006	Direct use	Direct use	Direct use	Direct use	MS ISO 11137-1:2010	Direct use	**Direct use**	Direct use	IDT	**TCVN 7393 : 2004**
9	Medical laboratories -- Requirements for safety	ISO 15190:2003	Direct use	Direct use	Direct use	Direct use	MS ISO 15190:2008	Direct use	**Direct use**	Direct use	IDT (TIS 2276-2549)	**TCVN 8332 : 2010**

NO.	TITLE OF STANDARDS	REFERENCES	STATUS OF ADOPTION AND VERSION OF INTERNATIONAL STANDARDS ADOPTED									
			BN	**KH**	**ID**	**LA**	**MY**	**MM**	**PH**	**SG**	**TH**	**VN**
10	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2006	Direct use	Direct use	Direct use	Direct use	MS ISO 11607-2:2009	Direct use	**Direct use**	Direct use	IDT in the process of adoption)	**TCVN 7394-2: 2008**
11	Clinical Investigation of Medical Devices for Human Subjects	ISO 14155-1:2003 ISO 14155-2:2003	Direct use		Direct use	Direct use	No corresponding national standard. Note: Will be tabled for adoption.	Direct use	**Direct use**	Direct use	IDT (ISO 14155:2011, in the process of adoption)	**TCVN 7704-1,2: 2007**

NO.	TITLE OF STANDARDS	REFERENCES	STATUS OF ADOPTION AND VERSION OF INTERNATIONAL STANDARDS ADOPTED									
			BN	**KH**	**ID**	**LA**	**MY**	**MM**	**PH**	**SG**	**TH**	**VN**
12	Biological Evaluation of Medical Devices	ISO 10993-1 to -18	Direct use	Direct use	Direct use	Direct use	i) MS ISO 10993-1:2005 ii) MS ISO 10993-3:2005 iii) MS ISO 10993-4:2010 iv) MS ISO 10993-13:2005 v) MS ISO 10993-14:2005 vi) MS ISO 10993-15:2005 vii) MS ISO 10993-16:2005 viii) MS ISO 10993-17:2005 Note: Will be tabled for adoption for ISO 10993 part 2, 5,6,7,8,9,10 ,11,12,18.	Direct use	**Direct use**	Direct use	IDT (TIS 2395 Part 1-7, 9-18, 2551)	**TCVN 7391-1:2004 2:2005 3:2005 4:2005 5:2005 6:2007 7:2004 9: 2013 10: 2007 11:2007 12:2007 13:2013 14: 2007 15:2007 16:2007 17:2007 18:2007**

NO.	TITLE OF STANDARDS	REFERENCES	STATUS OF ADOPTION AND VERSION OF INTERNATIONAL STANDARDS ADOPTED									
			BN	KH	ID	LA	MY	MM	PH	SG	TH	VN
13	Contact Lens	ISO 14729-2001	Direct use	Direct use	Direct use (SNI under development)	Direct use	MS ISO 14729:2009	Direct use	**Direct use**	Direct use	-	In the process of adoption
14	Contact Lens Substances	ISO 14730-2000	Direct use	Direct use	Direct use (SNI under development)	Direct use	MS ISO 14730:2009	Direct use	**Direct use**	Direct use	-	In the process of adoption

SECOND PRIORITY

NO.	TITLE OF STANDARDS	REFERENCES	STATUS OF ADOPTION AND VERSION OF INTERNATIONAL STANDARDS ADOPTED									
			BN	KH	ID	LA	MY	MM	PH	SG	TH	VN
1	Non-invasive sphygmomanometers -- Part 1: Requirements and test methods for non-automated measurement type	ISO 81060-1:2007	Direct use		Identical adoption SNI ISO 81060-1:2009, Tensimeter non-invasif (non-invasive sphygmomanometers) - Bagian 1: Persyaratan dan metode uji untuk tipe		No corresponding national standard. Note: Will be tabled for adoption.			Direct use	-	**TCVN 8333-1: 2010**

NO.	TITLE OF STANDARDS	REFERENCES	STATUS OF ADOPTION AND VERSION OF INTERNATIONAL STANDARDS ADOPTED									
			BN	KH	ID	LA	MY	MM	PH	SG	TH	VN
2	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	IEC60601-2-19:2009 Second edition	Direct use				MS IEC 60601-2-19:2007 – Adopted the old version (IEC 60601-2-19:1990 and its Amendment 1:1996) Note: Will be revised to adopt the latest publication this year.			Direct use	-	**TCVN 7303-2-19 : 2005**