Ackrediteringens omfattning / Scope of accreditation – Medical engineering and physics

Intertek Semko AB, Kista - **1003**

Standard designation	**CLC HD or EN**	**IEC Publ./ ISO Publ./ CEE Publ.**	**Comments Subcontractors, OSM/ CTL-decisions etc**
Medical electrical equipment Part 1: General requirements for safety	EN 60601-1: 1990	IEC 60601-1 2 ed. 1988	AP and APG equipment excluded. Sterilizing test acc. to 44.7 excluded
	EN 60601-1: 1990/ A1:1993	A1, 1991 to IEC 60601-1 2 ed. 1988	
	EN 60601-1: 1990 / A2: 1995	A2, 1995 to IEC 60601-1 2 ed. 1988	*
	EN 60601-1: 2006	IEC 60601-1 3 ed. 2005	Subclause 11.6.7 * sterilization
	EN 60601-1:2006 / A1:2013	A1, 2012 to IEC 60601-1 3 ed. 2012	
Medical electrical equipment - Part 1-1: General requirements for safety - collateral standard: Safety requirements for medical electrical systems		**IEC 60601-1-1 2 ed. 2000**	
Medical device software – Software life cycle processes	EN 62304:2006	IEC 62304 1 ed. 2006	
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	EN 60601-1-6:2010	IEC 60601-1-6 3 ed. 2010	
Medical devices – Application of usability engineering to medical devices	EN 62366:2008	IEC 62366 1 ed. 2007	
		A1, 2014 to IEC 62366 1 ed. 2007	

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Rättelse
Text ”Clause 48” och ”and 11.7” borttaget. Pernilla Carlsson 2016-04-15.

Medical electrical equipment Part 1-8: General	**EN 60601-1-8:2004**	**IEC 60601-1-8 1 ed. 2003**	

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requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	**EN 60601-1-8:2004 / A1:2006**	**A1, 2006 to IEC 60601-1-8 1 ed. 2003**	
Medical electrical equipment - Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8:2007	IEC 60601-1-8 2 ed. 2006	
		Am 1, 2012 to IEC 60601-1-8 2 ed. 2006	
Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators	EN 60601-2-12: 2006	IEC 60601-2-12 2 ed. 2001	
Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators		ISO 80601-2-12 1 ed. 2011	
Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems	EN 60601-2-13: 2006	IEC 60601-2-13 3 ed. 2003	
	EN 60601-2-13: 2006/A1	Am. 1 2007 to IEC 60601-2-13 3 ed. 2003	
Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation		ISO 80601-2-13 1 ed. 2011	
		A1, 2015 to ISO 80601-2-13 1 ed. 2011	

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Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	EN ISO 80601-2-55:2012	ISO 80601-2-55 1 ed. 2011	
Hoists for the transfer of disabled persons – Requirements and test methods	EN ISO 10535:2006	ISO 10535 2 ed. 2006	Subclause 7.2.1.6, 8 and 9 excluded
Equipment for measurement, control and laboratory use Part 1: General requirements	EN 61010-1: 2001	IEC 61010-1 2 ed. 2001	
	EN 61010-1: 2010	IEC 61010-1 3 ed. 2010	

Ändringar är markerade med fet stil.

Provtagning omfattas inte av ackrediteringen. Om laboratoriet ändå själv utför provtagning omfattas provningen inte av ackrediteringen.

Synpunkter och tolkningar omfattas inte av ackrediteringen. Om laboratoriet ändå redovisar synpunkter och tolkningar i provningsrapporten omfattas provningen inte av ackrediteringen.

Ackrediteringsomfattningen är flexibel enligt vad som anges i detta beslut. Förändrade metoder där förändringarna innefattas i den flexibla ackrediteringen får, även om nytt beslut inte har utfärdats, användas som ackrediterade metoder.

Changes are printed in bold type.

The accreditation does not cover sampling activities. If the laboratory, regardless of this, performs the sampling by itself, then the testing is not considered to be performed under accreditation.

The accreditation does not cover opinions and interpretations. If the laboratory, regardless of this, expresses opinions and/or provides interpretations in the test report, then the testing is not considered to be performed under accreditation.

The scope of accreditation is flexible according to specification in this decision. Changed methods where the changes are included in the flexible scope may, even if a new decision has not been issued, be used as accredited methods.