⊖ ⊙ ✈ / ⊜ ⊛ ☐ ◉ **John Lamb** 2 Issues | Importing 27 | <u>Out of Office:</u> PC SW SH <u>Future</u>

List of All Standards used in CE Files

10	EN 1041:2008	Information supplied by the manufacturer of medical devices
118	EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003) *Nov 2016*
146	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01) *Current*
196	EN 60601-1:2006	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance *BS-EN - A12:2014*
197	IEC 60601-1:2005	Medical electrical equipment -- Part 1: General requirements for basic safety and ✗ essential performance
198	EN 60601-1:2006/A1:2013	IEC 60601-1:2005/A1:2012 (new) *BS-EN +A12:2014*
199	IEC 60601-1:2005/A1:2012 (new)	EN 60601-1:2006/A1:2013 ✗
200	EN 60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests *replaced by 2015*
204	EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability *+ A12:2015*
208	EN 60601-1-10:2008	Medical electrical equipment -- Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers ✗
210	EN 60601-1-11:2010	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical ✗ equipment and medical electrical systems used in the home healthcare environment
230	EN 60601-2-10:2000	Medical electrical equipment -- Part 2-10: Particular requirements for the safety of nerve and muscle stimulators *- 2015*
232	EN 60601-2-10:2000/A1:2001	IEC 60601-2-10:1987/A1:2001 *- 2015*
354	ISO 14971:2007	
360	EN ISO 9001 2008	*- 2015*
361	BS EN ISO 15223-1:2012	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied *✓*
364	ISO 13465	Manufacturing procedures *Nuclear energy*