**Appendix 6.2 List of Harmonised Standards**

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| ***SN*** | ***Standard No.*** | ***Standard*** |
| ***1*** | ***EN ISO 13485:2016/A11:2021*** | ***Medical devices - Quality management systems - Requirements for regulatory purposes*** |
| ***2*** | ***EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020*** | ***Medical electrical equipment - Part 1: General*** ***requirements for basic safety and essential performance***  |
| ***3*** | ***EN 60601-1-2:2015+A1:2020*** | ***Medical electrical equipment - Part 1-2: General*** ***requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests***  |
| ***4*** | ***EN ISO 15223-1:2021*** | ***Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)*** |
| ***5*** | ***EN ISO 14971:2019/A11:2021***  | ***Medical devices - Application of risk management to medical devices***  |
| ***6*** | ***EN62366-1:2015+AC:2015+AC:2016+A1:2020***  | ***Medical devices -Part 1: Application of usability engineering to medical devices to medical devices***  |
| ***7*** | ***EN ISO 10993-1:2020*** | ***Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process***  |
| ***8*** | ***EN ISO 10993-5:2009*** | ***Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*** |
| ***9*** | ***EN ISO 10993-10:2013*** | ***Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*** |
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| ***10*** | ***EN ISO 14155:2020*** | ***Clinical investigation of medical devices for human subjects - Good clinical practice*** |
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