**Additional Check list Medical Device**

Information for Quotation

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| **1. Name of test specimen** |
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| **2. Manufacturer of medical device** |
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| **3. Description of medical device**  (Device, module, PCB, interface, function, etc.) |
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| **4. Medicine class of medical device** |
| I  IIa  IIb  III |
| **5. Which revision level EN 60601-1-2 shall be applied?** |
| EN 60601-1-2:2015  EN 60601-1-2: |
| **6. Additional requirements acc. EN 60601-2-X?** |
| no  yes  EN 60601-2- |
| **7. Range of use medical device** (EN 60601-1-2:2015) |
| Domestic Health Care  Professional Health Care |
| **8. Installation situation medical device** |
| Tabletop Unit  Floor mounted appliance  both |
| **9. Does medical device contain life support features / systems?** |
| no  yes  which |
| **10. Does medical device record physiological data?** |
| no  yes  ? explicate |
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| **11. Basis safety concept of medical device reference to EM-disturbance** (Description acc. EN 60601-1-2:2015 App. F) |
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| **12. Performance characteristics medical device**  **reference to EM-disturbance** (Specification acc. EN 60601-1-2:2015 App. F ) |
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| **13. How shall basis safety concept and performance characteristics during EMC tests  be monitored?** (Please take particular specifications of standard series EN 60601-2-X into lkjfhconsideration |
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| **14. Software version** |
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| **15. Any particular hardware/software needed for testing?** |
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| **16. Any additional device or simulators needed for testing?** |
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| **17. Any alarm limits adjusted?** |
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| **18. Document identification of risk assessment related to EM-disturbance** (Implementation acc. ISO 14971) |
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| **Please note that, without risk assessment a test plan generation is not possible and non- xdgfstandard** |
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