**Additional Check list Medical Device**

 Information for Quotation

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| **1. Name of test specimen** |
|       |
| **2. Manufacturer of medical device** |
|       |
| **3. Description of medical device** (Device, module, PCB, interface, function, etc.) |
|        |
| **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) |
|         |
| **12. Performance characteristics medical device**  **reference to EM-disturbance** (Specification acc. EN 60601-1-2:2015 App. F ) |
|        |
| **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 |
|         |
| **14. Software version** |
|       |
| **15. Any particular hardware/software needed for testing?** |
|       |
| **16. Any additional device or simulators needed for testing?** |
|       |
| **17. Any alarm limits adjusted?** |
|       |
| **18. Document identification of risk assessment related to EM-disturbance** (Implementation acc. ISO 14971) |
|       |
|  **Please note that, without risk assessment a test plan generation is not possible and non- xdgfstandard**  |
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