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**Appendix 1 – General Safety and Performance Requirements (GSPR)**

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| **Name of the medical device** |  |
| **Document no.** |  |

**Change history**

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **Version** | **Created by** | **Description of change** |
|  | 0.1 | Advisera | Basic document outline |
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| --- | --- | --- | --- | --- |
| GSPR clause number | Requirement | Applicable? (Yes/No) | … | …. |
| **GENERAL REQUIREMENTS** | | | | |
| 1 | Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks that may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state-of-the-art. |  |  |  |
| 2 | … |  |  |  |

…

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