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| **Essential Principles Checklist** |  |
| Identity of the IVD: |  |

| **Essential Principle** | **Applicable to the device?** | **Method Used to Demonstrate Conformity** | **Method Reference** | **Reference to Supporting Controlled Documents** |
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| **General Requirements** |  |  |  |  |
| 1.1 Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will 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 which 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. |  |  |  |  |
| 1.2 The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:* identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse
* eliminate risks as far as reasonably practicable through inherently safe design and manufacture
* reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms
* inform users of any residual risks.
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| 1.3 Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. |  |  |  |  |
| 1.4 The characteristics and performances referred to in Clauses 1.1, 1.2 and 1.3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer’s instructions. |  |  |  |  |
| 1.5 The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer. |  |  |  |  |
| 1.6 All known and foreseeable risks, and any undesirable effects, should be minimised and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use. |  |  |  |  |
| **Design and Manufacturing Requirements** |  |  |  |  |
| 2.1 Chemical, physical and biological properties. |  |  |  |  |
| 2.2 The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1.1 to 1.6 of the General Requirements. Particular attention should be paid to:* the choice of materials used, particularly as regards toxicity and, where appropriate, flammability
* the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device
* the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.
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| The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure. |  |  |  |  |
| ------------------------------- etc. -------------------------------------------- |  |  |  |  |