



**Medical Device Division
Department of Health**

**Medical Device Administrative Control System
Essential Principles Conformity Checklist
for In Vitro Diagnostic Medical Devices**

Manufacturer:

Brand Name and Model:

Clause	Essential Principle	Applicable	Method of Conformity	Identity of Specific Documents
General Requirements				
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, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and 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.			

2.	<p>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 risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:</p> <ul style="list-style-type: none"> • 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 reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and • inform users of any residual risks. 			
3.	<p>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.</p>			
4.	<p>The characteristics and performances referred to in Clauses A1, A2 and A3 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.</p>			
5.	<p>Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.</p>			
6.	<p>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.</p>			

Design and Manufacturing Requirements				
7.	Chemical, physical and biological properties			
7.1	The IVD medical devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in clause 1 to 6. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte (measurand) to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of its intended purpose.			
7.2	The IVD medical devices should be designed, manufactured and packaged 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 device.			
7.3	The IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the IVD medical device. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.			
7.4	IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the IVD medical device taking into account the device and the nature of the environment in which it is intended to be used.			
8.	Infection and microbial contamination			
8.1	The IVD medical devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to user, professional or lay, or, where applicable, other person . The design should: <ul style="list-style-type: none"> • allow easy and safe handling; and, where necessary: <ul style="list-style-type: none"> • reduce as far as reasonably practicable and appropriate any microbial leakage from the IVD medical device and/or microbial exposure during use; and • prevent microbial contamination of the IVD medical device or specimen where applicable, by the user, professional or lay, or other person. 			

8.2	IVD medical devices labelled either as sterile or as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.			
8.3	IVD medical devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.			
8.4	IVD medical devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
8.5	Packaging systems for non-sterile IVD medical devices should maintain the integrity and cleanliness of the device.			
9	IVD medical devices incorporating materials of biological origin			
9.1	<p>Where IVD medical devices include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for user, professional or lay, or other person.</p> <p>In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.</p>			
9.2	<p>Where IVD medical devices include human tissues, cells and substances, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for user, professional or lay, or other person.</p> <p>In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.</p>			

9.3	<p>Where IVD medical devices include cells and substances of microbial origin, the processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for user, professional or lay, or other person.</p> <p>In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.</p>			
10	Environmental properties			
10.1	<p>If the IVD medical device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.</p>			
10.2	<p>IVD medical devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:</p> <ul style="list-style-type: none"> • the risk of injury to user, professional or lay, or other person in connection with their physical and ergonomic features; • the risk of use error due to the ergonomic features, human factors and the environment in which the IVD medical device is intended to be used; • risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations thereof; • the risks associated with the use of the IVD medical device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use; • the risk associated with the possible negative interaction between software and the environment within which it operates and interacts; • the risks of accidental penetration of substances into the IVD medical device; • the risk of incorrect identification of specimens/samples; • the risks of reasonably foreseeable interference with other devices such as carry over between IVD medical devices. 			

10.3	IVD medical devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to IVD medical devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
10.4	IVD medical devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.			
10.5	IVD medical devices should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
11	Performance characteristics			
11.1	IVD medical devices should be designed and manufactured in such a way that the performance characteristics support the intended use, based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy which is trueness and precision (repeatability and reproducibility), control of known relevant interference and limits of detection. These performance characteristics need to be maintained during the lifetime of the IVD medical device as indicated by the manufacturer.			
11.2	Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through available reference measurement procedures and/or available reference materials of a higher order.			
11.3	Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.			
12	Protection against radiation			
12.1	IVD medical devices should be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other person to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as reasonably practicable and appropriate.			
12.2	When IVD medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should as far as reasonably practicable and appropriate be: <ul style="list-style-type: none"> • designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and • fitted with visual displays and/or audible warnings of such emissions. 			

13	IVD medical devices that incorporate software and standalone IVD medical device software		
13.1	For IVD medical devices which incorporate software or for standalone software that are IVD medical devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.		
14	IVD medical devices connected to, or equipped with, an energy source		
14.1	IVD medical devices where the safety of the patient depends on an internal power supply in the IVD medical device, should be equipped with a means of determining the state of the power supply.		
14.2	IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.		
14.3	IVD medical devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.		
14.4	IVD medical devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the IVD medical device is installed and maintained as indicated by the manufacturer.		
15	Protection against mechanical and thermal risks		
15.1	IVD medical devices should be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts.		
15.2	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.		
15.3	IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.		

15.4	IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source.			
15.5	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle should be designed and constructed in such a way as to minimize all possible risks.			
15.6	IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during use.			
15.7	Accessible parts of the IVD medical devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.			
16	Protection against the risks posed by IVD medical devices for self-testing			
16.1	IVD medical devices for self-testing should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.			
16.2	IVD medical devices for self-testing should be designed and manufactured in such a way as to reduce as far as reasonably practicable the risk of error by the lay person in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.			
16.3	IVD medical devices for self-testing should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.			
17	Label and Instructions for Use			
17.1	Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.			
18	Performance evaluation including analytical performance and, where appropriate, clinical performance			

18.1	<p>For an IVD medical device a performance evaluation should be conducted in accordance with GHTF guidance. The performance evaluation should review analytical performance data and, where appropriate, clinical performance data in the form of any:</p> <ul style="list-style-type: none"> • literature; • performance study reports; and • experience gained by routine diagnostic testing. <p>to establish that the IVD medical device achieves its intended performance during normal conditions of use and that the known, and foreseeable risks, and any undesirable effects, are minimised and acceptable when weighed against the benefits of the intended performance.</p>			
18.2	<p>Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.</p>			

I confirm that I have neither amended the wording in this form, nor otherwise altered the form in any material manner, apart from filling in the blanks.

I declare that the information provided in this form is accurate and correct and the device conforms to all the applicable requirements stipulated above.

Signature:

Name:

Position:

The Applicant (Local Responsible Person):

Date:

Company Chop