Hangzhou CIRS Co., Limited (CIRS China)
11F,1# Building Dongguan High Tech Zone, 288# Qiuyi Road,
Binjiang District, Hangzhou, Zhejiang, China
Tel: 0086 571 87206541 Fax: 0086 571 87206533
Email: Edwin.wen@cirs-group.com

List of Basic Requirements for Safety and Effectiveness of Medical Device

Article No.	Requirements	Applicable	Method for proving the conformity	documents for providing objective evidences for conformity
A	**General Principle**			
A1	Design and manufacture of medical device shall ensure that such medical device will be used by intended users (if applicable) with certain technical knowledge, experience, educational background, training experience and medical or hardware conditions, based on intended use method prescribed by manufacturer under the intended conditions and usage without causing damage to medical environment, patients' safety or safety and health of users and other people. During the use process, potential risks may be acceptable when compared with benefits of patients and advanced methods of protecting health and safety shall be in place.			
A2	The design and manufacture of the medical device shall follow the safety principles and take into account existing technical capacity. If adopt risk control, it shall ensure that the residual risk of each hazard is acceptable. Manufacturer shall adopt the following principles in order to: (1) Identify known or predictable hazard and assess the risks caused by intended use and predictable improper use			

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	(2) Eliminate risks as much as possible during the design and manufacture process (3) Take full protective measures (such as alarm) to minimize residual risks (4) Notify residual risks.			
A3	Medical device shall achieve its expected performance and meet the requirements of applicable scope under the use conditions specified.			
A4	Degree of degradation of features and property of medical device will not affect its safety within the life cycle under the normal usage and maintenance conditions			
A5	Design, manufacture and packaging of medical device shall ensure that transportation or storage conditions specified in its instruction for use (such as change of temperature and humidity) will not have adverse impacts on product features and performance.			
A6	All risks and unintended effects shall be minimized and acceptable to ensure the benefits outweigh the risks in normal use.			
B	**Basic Principles of Safety Performance of Medical Device**			
B1	Chemical, physical and biological properties			
B1.1	Product materials shall meet the requirements given in Section A, in particular: (1) The selection of materials shall pay particular attention to their toxicity and inflammability (if applicable). (2) Compatibility of materials with biological tissue, cell and body fluid shall be taken into consideration based on intended use. (3) The selection of materials shall consider hardness, wear resistance and fatigue strength			

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	and other properties (if applicable).			
B1.2	Medical device shall be designed, manufactured and packed to minimize the risks brought by pollutants and residue to the personnels engaged in transportation, storage and use as well as patients. In particular, attention shall be paid to duration and frequency of contact with exposed human tissue.			
B1.3	Medical device shall be well designed and manufactured to guarantee usage safety when product comes into contact with other materials, substances and gas during normal use or conventional procedures. Where medical device is used for drug administration, such products shall be well designed and manufactured complying with relevant regulations and limitations concerning pharmaceutical management without changing the product performance complying with its intended use.			
B1.4	Medical device shall be designed and manufactured to minimize the risks caused by substances filtered out or leaked, and particular attention shall be paid to carcinogenicity, teratogenicity and reproductive toxicity.			
B1.5	Medical device design and manufacture should consider the features of products and its service environment during the intended use of products to minimizing the risks caused by substance going into or out of the products accidentally.			
B2	**Infection and Microbial Contamination**			
B2.1	Medical device shall be designed and manufactured to minimize the risk of infecting			

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	patients, users and other people. Design shall meet the following requirements: (1) Easy to operate (2) Minimize the leakage of micro-organism from the device and/or exposure of micro-organism during operation (3) Prevent the microbial contamination of human on devices and samples.			
B2.2	The medical device with microbiological requirements shall comply with the microbiological requirements before use.			
B2.3	The sterile medical device shall comply with the sterility requirements before use.			
B2.4	Sterile medical device or medical device with microbiological requirements shall be processed, manufactured or sterilized with validated methods.			
B2.5	Sterile medical device shall be manufactured under the corresponding controlled state (such as environment with corresponding purification degree).			
B2.6	Package of non-sterile medical device shall preserve the product integrity and cleanliness. For products requiring sterilization before use, its package shall minimize the risks of microbial contamination and suit relevant sterilization methods provided by manufacturer.			
B2.7	Where same or similar medical device may be sold as sterile or non-sterile phases, package or label of such products shall differentiate the difference			
B3	**Drug-device Combination Product**			
B3.1	Validate the safety, quality and performance of the drug and			

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	the drug-device combination product.			
B4	**Biogenic Medical Device**			
B4.1	For medical device containing animal origin tissue, cell and other substances, such animal origin tissue, cell and substances shall conform to related laws and regulations in China and comply with its intended use. Animal origin materials shall be well preserved for future reference. Processing, preservation, testing and treatment process of animal tissue, cell and other substances shall provide optimal safety protection for patients, users and other people (if applicable). In particular, validated removal or inactivation methods shall be used to deal with virus and other infection agents.			
B4.2	For medical device containing human tissue, cell and other substances, proper source or donors shall be selected for reducing the risk of infection. Processing, preservation, testing and treatment process of human tissue, cell and other substances shall provide optimal safety protection for patients, users and other people (if applicable). In particular, validated removal or inactivation methods shall be used to deal with virus and other infection agents.			
B4.3	For medical device containing micro-organism cell and other substances, processing, preservation, testing and treatment process of cell and other substances shall provide optimal safety protection for patients, users and other people (if applicable). In particular, validated removal or inactivation methods shall be used to deal with virus and			

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	other infection agents.			
B5	**Environmental Characteristics**			
B5.1	Where medical device is intended to be used in conjunction with other medical device or equipment, the overall safety of the system after the combined application shall be guaranteed without impairing the performance of device or equipment. Any restrictions on combined application shall be specified in the label and (or) instruction for use. The connection system that shall be operated by the user, such as liquid, gas delivery, or mechanical coupling shall be designed and structured to minimize the risks caused by improper connection.			
B5.2 B5.2.1	Medical device shall be well designed and manufactured for eliminating and reducing the following risks as much as possible: Risk of causing injury to patients, users or other people because of physical or ergonomics effectiveness reasons;			
B5.2.2	Risks of improper operation caused by ergonomics, human factors and operating environmental factors;			
B5.2.3	Reasonably foreseeable external factors or environment conditions related risks, such as magnetic field, external electromagnetic effects, electrostatic discharge, radiation from diagnosis and treatment, pressure, humidity, temperature and pressure and changes of accelerated speed			
B5.2.4	Risks caused by the product when contacting with materials, liquid and gases during normal operation and use;			
B5.2.5	Risks caused by compatibility			

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	of software and operating environment;			
B5.2.6	Risk of accident entry of substances;			
B5.2.7	Risk of mutual interference for products that are used in conjunction with other medical devices in the clinical diagnosis and treatment;			
B5.2.8	Risks of medical device that can't be maintained or calibrated (such as implantable devices) because of materials ageing, reduced measurement or control accuracy.			
B5.3	Medical device shall be designed and manufactured to minimize the risks of combustion and explosion under the state of normal use or single failure, especially medical device exposed to combustible or inflammable substances or used in conjunction with combustible or inflammable substances during the process of intended use.			
B5.4	The medical device shall be adjusted, calibrated and maintained to ensure the design and manufacture can guarantee the safe operation of corresponding processes.			
B5.5	The medical device shall be designed and manufactured to facilitate the safe disposal of wastes.			
B6	**Medical Device with Diagnostic or Measuring Function**			
B6.1	The medical device with diagnostic or measuring function shall be designed and manufactured to take full account of its accuracy, precision and stability. Manufacturer shall specify the limiting value about accuracy.			
B6.2	Given the intended use of medical device, scope of any measurement, monitoring or display value shall be designed			

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	based on the principle of ergonomics.			
B6.3	The measured values shall be in metric units commonly used in China and can be understood by users.			
B7	**Radiation Protection**			
B7.1	General requirements: The medical device shall be designed, manufactured and packed to minimize the radiation to patients, users and others while not affecting the therapeutic and diagnostic functions.			
B7.2	Expected radiation: medical device use radiation for therapy and diagnostics purpose shall have controllable radiation dose. And the medical device shall be designed and manufactured to ensure the repeatability and errors of relevant adjustable parameters are within the allowable range. If the radiation expected of the device is potentially harmful, the device shall be equipped with appropriate sound and light alarm for the radiation.			
B7.3	Non-expected radiation: medical device shall be designed and manufactured to minimize the exposure of patients, users and other people to non-expected, spurious or scattered radiation.			
B7.4	Ionizing radiation: for medical device that is expected to emit ionizing radiation, its design and manufacturing shall ensure that measurement, geometric distribution and energy distribution (or quality) of radiation emitted is controllable. Medical device emitting ionizing radiation (intended for radiology diagnosis) shall be designed and manufactured to reach the clinical image quality			

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	required and minimize absorbed dose of radiation received by patients and users. Medical device producing ionizing radiation (intended for radiologic treatment) shall be designed and manufactured to realize the reliable monitoring and control over the beam dose, beam type, energy, and energy distribution (when applicable).			
B8	**Medical Device with Software or Stand-alone Medical Software**			
B8.1	Medical device integrating electronic programmable system (including software) or stand-alone medical device software shall be designed to guarantee repeatability, reliability and performance. In case of single failure, proper measures shall be applied to remove and reduce risks as much as possible.			
B8.2	For medical device integrating software or stand-alone medical device software, its software must be confirmed according to the most advanced technology level (It is needed to consider R&D cycle, risk management, verification and validation).			
B9	**Active Medical Device and Device Connecting with Active Element**			
B9.1	For the active medical device of a single fault, measures shall be taken to eliminate or reduce risks as much as possible.			
B9.2	Where patient safety is guaranteed by medical device with internal power supply, such medical device shall have the function of inspecting power supply status.			
B9.3	Where patient safety is guaranteed by medical device with external power supply, such medical device shall have the alarm system for indicating power failure			

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B9.4	Medical device intended for monitoring one or more clinical parameters of patients shall be equipped with proper alarm system for giving warning to users when life health of patients is seriously deteriorated or patients are in danger.			
B9.5	The design and manufacturing of medical devices shall contain the methods to reduce electromagnetic interference.			
B9.6	Medical device shall be designed and manufactured to minimize the risk of electromagnetic interference as such interference may affect the operation of the device and other devices under the normal sevice environment.			
B9.7	When installation and maintenance is carried out based on requirements of manufacturer, medical device shall be designed and manufactured to minimize the risk of accidental electric shock of patients, users and other people under the states of normal use or single failure.			
B10	**Mechanical Risk Protection**			
B10.1	Medical device shall be designed and manufactured to protect patients and users against mechanical risks caused by mobile resistance, unstable components and moving parts.			
B10.2	Except that vibration is specific performance of medical device, medical device shall be designed and manufactured to minimize the risks caused by product vibration. If feasible, proper measures shall be applied to limit or restrict vibration (especially vibration source).			
B10.3	Except that noise is the specific performance of medical device,			

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	medical device shall be designed and manufactured to minimize the risks caused by product noise. If feasible, proper measures shall be applied to limit or restrict noise (especially noise source)			
B10.4	The terminals and connectors for connecting electricity or gas or providing hydraulic pressure and pneumatic pressure operated by the user shall be designed and constructed to minimize the operation risk.			
B10.5	If the some part of the medical device has to be connected or reconnected before or in use, the medical device shall be designed and manufactured to minimize the risk of connection errors.			
B10.6	The accessible medical device parts and its surrounding areas (excluding the parts or areas providing heat or reaching the given temperatures) shall not reach dangerous temperature in normal use.			
B11	**Protection of Risks for medical device that Provide Energy or Substance to the Patients**			
B11.1	Medical device providing substance or energy to patients shall be designed and constructed to accurately set and maintain the output, in order to ensure the safety of patients and users.			
B11.2	If insufficient output may lead to risks, medical device shall have methods to prevent and/or indicate “insufficient output”. Such products shall have proper prevention methods to prevent energy or substances reaching hazard level from being output accidentally.			
B11.3	Medical device shall be clearly labeled with the functions of controls and indices. If device operation may indicate the use			

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	instructions, operating state or adjustment parameters of system, such information shall be easy to understand			
B12	**Protection to Non-professional User against Application Risks**			
B12.1	Medical device shall be designed and manufactured and take the technology known by non-professional users and service environment into account, sufficient instructions shall be provided to facilitate understanding and use.			
B12.2	The medical device shall be designed and manufactured to minimize the risks of operational errors and misunderstanding of non-professional users.			
B12.3	Medical device shall try to have procedures that can be used by non-professional users to inspect whether product operates normally during use.			
B13	**Label and Instruction for Use**			
B13.1	Considering the training and knowledge received by users and for the purposes of making users obtain full information to identify manufacturer, safely use of the device and guarantee expected performance, such information shall be easy to understand.			
B14	**Clinical Evaluation**			
B14.1	Materials about clinical evaluation of medical device shall be provided in accordance with existing laws and regulations in China.			
B14.2	Clinical trial shall be in strict compliance with Declaration of Helsinki. Approval of clinical trial shall conform to existing laws and regulations in China.			
Note	1 If applicable if in Column 3, indicate “Yes”. If not applicable, indicate “No” and state relevant reasons. 2. Fill in Column 4 methods proving that the medical device meets the basic requirements for safety and effectiveness. Methods for proving the conformity shall include			

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	(1) Recognized international, national and industry standards; (2) Comply with the relevant national standards, industrial standards, and international standards concerning medical devices. (3) Verification methods generally accepted in the industry; (4) Applicable verification methods of manufacturer; (5) Comparison with products of same kind already launched. (6) Clinical evaluation 3. The location and number of evidences provided for conformity shall be noted in the registration application materials. For documents included in product registration application materials, their locations shall be specified, for example, VIII. Registration inspection report (medical electric safety: prevention of mechanical risks); Section 4.2 of the instruction. For documents not included in the product registration application materials, their names and numbers in the quality control system documents shall be noted for inspection.