东软医疗系统股份有限公司
NEUSOFT MEDICAL SYSTEMS CO., LTD.

MDD Essential Requirements Checklist

According to Directive 93/42/EEC

Product Name	**Multi-slice CT Scanner System**	
Product Model	**NeuViz Prime**	
Activity	**Signature/Date**	**Title**
Author	梁铁城 2021-5-26	QR Engineer
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Approval	田月辉 2021-5-26	QR Manager
Effective Date	2021-5-26	

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	Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
I.	**GENERAL REQUIREMENTS**				
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended 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. This shall include: ▪ reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 EN ISO 13485 Procedure: Product realization process Risk management control procedure	See EN/IEC report Risk management plan Risk Management report Clinical Evaluation Report Certificate of compliance EN ISO 13485: 2016	Ok
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • inform users of the residual risks due to any shortcomings of the protection measures adopted.	A A A A A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 EN ISO 13485 Procedure: Product realization process Risk management control procedure	See EN/IEC report Risk management plan Risk Management report Clinical Evaluation Report Certificate of compliance EN ISO 13485: 2016	Ok
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 EN ISO 13485 Meddev 2.7.1 Procedures: Product realization process	See EN/IEC report Product verification report Clinical evaluation report Certificate of compliance EN ISO 13485: 2016	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
4.	The characteristics and performances referred to in sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients 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.	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 EN ISO 13485 Procedures: Product realization process Risk management control procedure	See EN/IEC report Risk management plan Risk Management report Clinical Evaluation Report Product validation plan Certificate of compliance EN ISO 13485: 2016	Ok
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	A	EN/IEC 60601-1 EN/IEC 60601-1-6 EN/IEC 62366 EN ISO 14971 Procedures: Product realization process Risk management control procedure	See EN/IEC report Risk management plan Risk Management report Product information manual	Ok
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended.	A	EN ISO 14971	Risk management file	Ok
6a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	A	Meddev 2.7.1	Clinical evaluation report	Ok
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**				
7.	**Chemical, physical and biological properties**				
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section 1 on the "General requirements". Particular attention must 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 and body fluids, taking account of the intended purpose of the device. ● where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	A	EN/IEC 60601-1 EN/IEC 60601-1-6 EN/IEC 62366 EN ISO 14971 EN ISO 10993 Procedures: Product realization process Risk management control procedure	See EN/IEC report Biocompatibility Assessment report Risk management plan Risk Management report	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
7.2	The devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure.	A	EN/IEC 60601-1 EN/IEC 60601-1-6 EN/IEC 62366 EN ISO 14971 EN ISO 10993 Procedures: Risk management control procedure	See EN/IEC report Biocompatibility Assessment report Risk management plan Risk Management report Product information manual	Ok
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use.	A	EN/IEC 60601-1 EN ISO 14971 EN ISO 10993 Procedures: Risk management control procedure	See EN/IEC report Biocompatibility Assessment report Risk management plan Risk Management report	Ok
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety, and usefulness of the substance must be verified by analogy with the appropriate methods specified in Annex I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2001 (1) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.	NA		No integral part or substance used separately	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
7.4 (continued) Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.	N/A		No integral part or substance used separately	
7.5 The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.	A	EN/IEC 60601-1 EN ISO 14971 Procedures: Product realization process Risk management control procedure	See EN/IEC report Risk management plan Risk Management report	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	7.5 (continued) If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	NA		No substances used in the device	
7.6	The devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	A	EN/IEC 60601-1 EN ISO 14971 Procedures: Product realization process Risk management control procedure	See EN/IEC report Risk management plan Risk Management report	Ok
8.	**Infection and microbial contamination**				
8.1	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.	A	EN/IEC 60601-1 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Risk management plan Risk Management report	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified Bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells, and substances of animal origin must be carried out so as to provide optimal security. In particular, safety with regard to viruses and other **transmissible** agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	NA		No use of animal tissues	
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	NA		Devices does not delivered in a sterile state	
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method.	NA		Devices does not delivered in a sterile state	
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.	NA		Devices does not intended to be sterilized	
8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.	A	EN ISO 13485 Product realization process	packing testing report	OK
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	NA		The device does not use in both sterile and non-sterile condition	
9.	**Construction and environmental properties**				
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performance of the devices. Any restrictions on use must be indicated on the label or in the instruction for use.	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Product information manual	Ok

	Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
9.2	Devices must be designed and manufactured in such a way as to remove or minimise as far as possible: • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features, • risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure, and acceleration, • the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, • risks arising where maintenance or calibration are not possible (as with implants) from ageing of the materials used or loss of accuracy of any measuring or control mechanism.	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report Risk management plan Risk Management report Clinical Evaluation Report	Ok
9.3	Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition.	A	EN/IEC 60601-1 EN ISO 14971 UL 94 Procedure: Risk management control procedure	EN/IEC 60601-1 TEST REPORT Risk management report	Ok
	Particular attention must be paid to devices whose intended use includes exposure to flammable substances which could cause combustion.	NA		Not intended use includes exposure to flammable substances	-
10.	**Devices with a measuring function**				
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Risk management plan Risk Management report	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device	A	EN/IEC 60601-1-6 EN/IEC 62366 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Risk management plan Risk Management report	Ok
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC. (OJ No L 39, 15. 2. 1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ No L 357, 7. 12. 1989, p. 28))	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Risk management plan Risk Management report	Ok
11.	**Protection against radiation**				
11.1	*General*	A	EN/IEC 60601-1 EN/IEC 60601-1-3 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Risk management plan Risk Management report	Ok
11.1.1	Devices shall be designed and manufactured such that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.				
11.2	*Intended radiation*	A	EN/IEC 60601-1 EN/IEC 60601-1-3 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report	Ok
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibilty and tolerance of relevant variable parameters.				
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	A	EN/IEC 60601-1 EN/IEC 60601-1-3 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
11.3 *Unintended radiation* 11.3.1 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is be reduced as far as possible.	A	EN/IEC 60601-1 EN/IEC 60601-1-3 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
11.4 11.4.1	*Instructions* The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	A	EN/IEC 60601-1 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-44 EN/IEC 62366 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report	Ok
11.5 11.5.1	*Ionising radiation* Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended uses.	A	EN/IEC 60601-1 EN/IEC 60601-1-3 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report	Ok
11.5.2	Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way, as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.	A	EN/IEC 60601-1 EN/IEC 60601-1-3 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report	Ok
11.5.3	Devices emitting ionising radiation intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of the radiation.	NA		No therapeutic radiology emitting.	
12. 12.1	**Requirements for medical devices connected to or equipped with an energy source** Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN/IEC 62304 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report	Ok
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN/IEC 62304 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report Risk management plan Risk Management report Product verification report Product validation report	

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	NA		Not depends on an internal power supply	
12.3	Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.	NA		Not depends on an external power supply	-
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	NA		No monitor function	
12.5	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	A	EN/IEC 60601-1-2 EN ISO 14971 Procedure: Risk management control procedure	EN/IEC 60601-1-2 test report Risk management plan Risk Management report	Ok
12.6	*Protection against electrical risks* Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly.	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	EN/IEC test report Risk management plan Risk Management report	Ok
12.7 12.7.1	*Protection against mechanical and thermal risks* Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	EN/IEC test report Risk management plan Risk Management report	Ok
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible 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.	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	EN/IEC test report Risk management plan Risk Management report	Ok
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	EN/IEC test report Risk management plan Risk Management report	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
12.7.4	The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimise all possible risks.	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	EN/IEC test report Risk management plan Risk Management report	Ok
12.7.5	Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	A	EN/IEC 60601-1 EN/IEC 60601-2-44 EN ISO 14971 Procedure: Risk management control procedure	EN/IEC test report Risk management plan Risk Management report	Ok
12.8	*Protection against the risks posed to the patient by energy supplies or substances*	A	EN ISO 13485 EN 60601-2-44 EN ISO 14971 Risk management control procedure	IEC 60601-2-44 test report Risk management report	Ok
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.				
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	A	EN ISO 13485 EN 60601-2-44 EN ISO 14971 Risk management control procedure	IEC 60601-2-44 test report Risk management report	Ok
12.9	The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	A	EN/IEC 60601-1 EN/IEC 60601-1-6 EN/IEC 60601-2-44 EN/IEC 62366 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Risk management plan Risk Management report	Ok
13.	**Information supplied by the manufacturer**				

	Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
13.1	Each device must be accompanied by the information needed to use it safely **and properly**, taking account of the training and knowledge of the potential users**, and to identify the manufacturer.** This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Product information manual Label manual Risk management plan Risk Management report	Ok
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN ISO 14971 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Product information manual Label manual Risk management plan Risk Management report	Ok
13.3	*The label* must bear the following particulars: a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community;	A	EN ISO 13485 EN 60601-1 EN ISO 15223-1 EN 1041 EN 980	IEC 60601-1 test report Instruction for use Product information guide Label manual	Ok
	b) the details strictly necessary for the user to identify the device and the contents of the packaging; especially for the users;	A	EN ISO 13485 EN 60601-1 EN ISO 15223-1 EN 1041 EN 980	IEC 60601-1 test report Instruction for use Product information guide Label manual	Ok
	c) where appropriate, the word "STERILE";	NA		Not sterile equipment	-

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
d) where appropriate, the batch code, preceded by the word "LOT", or the serial number;	A	EN ISO 13485 EN 60601-1 EN ISO 15223-1 EN 1041 EN 980	IEC 60601-1 test report Instruction for use Product information guide Label manual	Ok
e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	NA		Not such equipment	-
f)where appropriate, an indication that the device is for single use; A manufacturer's indication of single use must be consistent across the Community;	NA		Not such equipment	-
g) if the device is custom made, the words "custom made device"; g) if the device is custom made, the words "custom made device";	NA		Not such equipment	-
h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations";	NA		Not such equipment	-
i) any special storage and/or handling conditions;	A	EN ISO 13485 EN 60601-1 EN 1041	IEC 60601-1 test report Instruction for use Product information guide Label manual	Ok
j) any special operating instructions;	A	EN ISO 13485 EN 60601-1 EN 1041	IEC 60601-1 test report Instruction for use Product information guide Label manual	Ok
k) any warnings and/or precautions to take;	A	EN ISO 13485 EN 60601-1 EN60601-2-44 EN 60825-1 EN ISO 15223-1 EN 1041 EN 980	IEC 60601-1 test report IEC 60601-2-44 test report Instruction for use Product information guide Label manual	Ok
l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number;	A	EN ISO 13485 IEC 60601-1 EN ISO 15223-1 EN 980	IEC 60601-1 test report Label manual	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
m) where applicable, method of sterilisation.	NA		Not such equipment	-
n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	NA		Not such equipment	-
13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	NA		The intended purpose is obvious	Ok
13.5 Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	A	EN/IEC 60601-1 EN/IEC 60601-1-6 EN/IEC 62366 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
13.6 Where appropriate, the instructions for use must contain the following particulars: a) the details referred to in 13.3, with the exception of d) and b) the performances referred to in section 3 and any undesirable side effects; c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; e) where appropriate, information to avoid certain risks in connection with implantation of the device; f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the device to be re-sterilised, and any restriction on the number of reuses. Where devices are supplied with the intention that they may be sterilised before use, the instructions for cleaning and sterilisation must be that, if correctly followed, the device will still comply with the requirements in Section I;	A	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-1-3 EN/IEC 60601-1-6 EN/IEC 60601-2-28 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 EN ISO 13485 Procedure: Product realization process Risk management control procedure	See EN/IEC report User manual Product information manual Risk management plan Risk Management report Certificate of compliance EN ISO 13485: 2016	Ok

Essential Requirements acc. to Annex I of the MDD (93/42/EEC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request i) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.) j) in the case of devices emitting radiation for medical purpose, details of the nature, type intensity and distribution of this radiation The instruction for use must also include details, allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: k) precautions to be taken in the event of changes in the performance of the device; l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.; m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; n) precautions to be taken against any special, unusual risks related to the disposal of the device; o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; p) degree of accuracy claimed for devices with a measuring function. q) date of issue or the latest revision of the instructions for use.				Ok

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
1.	**ESSENTIAL HEALTH AND SAFETY REQUIREMENTS**			
1.1.	GENERAL REMARKS			
1.1.1	**Definitions** For the purpose of this Annex: (a) 'hazard' means a potential source of injury or damage to health; (b) 'danger zone' means any zone within and/or around machinery in which a person is subject to a risk to his health or safety; (c) 'exposed person' means any person wholly or partially in a danger zone; (d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery; (e) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation; (f) 'guard' means a part of the machinery used specifically to provide protection by means of a physical barrier; (g) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard; (h) 'intended use' means the use of machinery in accordance with the information provided in the instructions for use; (i) 'reasonably foreseeable misuse' means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.	A		Defined terms necessary for understanding EHSR of MD	OK
1.1.2	**Principles of safety integration** (a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof. The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping. (b) In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given: — eliminate or reduce risks as far as possible (inherently safe machinery design and construction), — take the necessary protective measures in relation to risks that cannot be eliminated, — inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment. (c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably fo reseeable misuse thereof. The machinery must be designed and constructed in such a	NA		Principles of safety integration specific to medical devices described in MDD Annex I, ER 1,2,3, 4, 5 and EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways — which experience has shown might occur — in which the machinery should not be used. (d) Machinery must be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment. (e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.				
1.1.3	**Materials and products** The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.	NA		Covered by MDD Annex I, ER 7	-
1.1.4.	**Lighting** Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity. Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting. Internal parts requiring frequent inspection and adjustment, and maintenance areas must be provided with appropriate lighting.	NA		No integral lighting, not requiring a higher level of luminance than is likely to be provided by the ambient lighting	-
1.1.5	**Design of machinery to facilitate its handling** Machinery, or each component part thereof, must: — be capable of being handled and transported safely, — be packaged or designed so that it can be stored safely and without damage. During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions. Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must: — either be fitted with attachments for lifting gear, or — be designed so that it can be fitted with such attachments, or — be shaped in such a way that standard lifting gear can easily be attached. Where machinery or one of its component parts is to be moved by hand, it must: — either be easily moveable, or — be equipped for picking up and moving safely. Special arrangements must be made for the handling of tools and/or machinery parts which, even if lightweight, could be hazardous.	NA		Covered by MDD Annex I, ER 5 and EN ISO 14971, Annex E,H	-
1.1.6	**Ergonomics** Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by	NA		Covered by MDD Annex I, ER 7	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	the operator must be reduced to the minimum possible, taking into account ergonomic principles such as: — allowing for the variability of the operator's physical dimensions, strength and stamina, — providing enough space for movements of the parts of the operator's body, — avoiding a machine-determined work rate, — avoiding monitoring that requires lengthy concentration, — adapting the man/machinery interface to the foreseeable characteristics of the operators.				
1.1.7	**Operating positions** The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen. If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards. Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.	NA		Covered by MDD Annex I, ER 7, 9, 11	-
1.1.8	**Seating** Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats. If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery. The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator. If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.	NA		Work station is not an integral part of the equipment.	-
1.2.	CONTROL SYSTEMS				
1.2.1	**Safety and reliability of control systems** Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that: — they can withstand the intended operating stresses and external influences, — a fault in the hardware or the software of the control system does not lead to hazardous situations, — errors in the control system logic do not lead to hazardous	NA		Covered by MDD Annex I, ER 12.1, 12.9 and EN/IEC 60601-1	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	situations, — reasonably foreseeable human error during operation does not lead to hazardous situations. Particular attention must be given to the following points: — the machinery must not start unexpectedly, — the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations, — the machinery must not be prevented from stopping if the stop command has already been given, — no moving part of the machinery or piece held by the machinery must fall or be ejected, — automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded, — the protective devices must remain fully effective or give a stop command, — the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery. For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.				
1.2.2.	**Control devices** Control devices must be: — clearly visible and identifiable, using pictograms where appropriate, — positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity, — designed in such a way that the movement of the control device is consistent with its effect, — located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant, — positioned in such a way that their operation cannot cause additional risk, — designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action, — made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces. Where a control device is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to confirmation, where necessary. Control devices must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles. Machinery must be fitted with indicators as required for safe operation. The operator must be able to read them from the control position. From each control position, the operator must be able to ensure that no-one is in the danger zones, or the control system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone. If neither of these possibilities is applicable, before the	A	Partially covered by MDD Annex I, ER 12, ER 12.9 and EN/IEC 60601-1 EN/IEC 60601-1-6 EN/IEC 60601-2-44 EN/IEC 62366 EN/IEC 62304 EN ISO 14971 Procedure: Risk management control procedure	See EN/IEC report Risk management plan Risk Management report	OK

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up. If necessary, means must be provided to ensure that the machinery can be controlled only from control positions located in one or more predetermined zones or locations. Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops. When machinery has two or more operating positions, each position must be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.				
1.2.3.	**Starting** It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose. The same requirement applies: — when restarting the machinery after a stoppage, whatever the cause, — when effecting a significant change in the operating conditions. However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation. For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation. Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stopping must be performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.	NA		Covered by MDD Annex I, ER 12., EN/IEC 60601-1	-
1.2.4.	**Stopping**				
1.2.4.1	**Normal stop** Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop. Each workstation must be fitted with a control device to stop some or all of the functions of the machinery, depending on the existing hazards, so that the machinery is rendered safe. The machinery's stop control must have priority over the start controls. Once the machinery or its hazardous functions have stopped, the energy supply to the actuators concerned must be cut off.	NA		Covered by MDD Annex I, ER 12	-
1.2.4.2.	**Operational stop** Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained.	NA		Covered by MDD Annex I, ER 12.	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
1.2.4.3.	**Emergency stop** Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. The following exceptions apply: — machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken, — portable hand-held and/or hand-guided machinery. The device must: — have clearly identifiable, clearly visible and quickly accessible control devices, — stop the hazardous process as quickly as possible, without creating additional risks, — where necessary, trigger or permit the triggering of certain safeguard movements.	NA		Covered by MDD Annex I, ER 12.1, 12.2 and EN/IEC 60601-1	-
1.2.4.4.	**Assembly of machinery** In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.	NA		Covered by MDD Annex I, ER 12., EN/IEC 60601-1	-
1.2.5.	**Selection of control or operating modes** The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop. If machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it must be fitted with a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode. The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator. If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously: — disable all other control or operating modes, — permit operation of hazardous functions only by control devices requiring sustained action, — permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences, — prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors. If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone. In addition, the operator must be able to control operation of the parts he is working on from the adjustment	NA		Covered by MDD Annex I, ER 12., EN/IEC 60601-1, EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	point.				
1.2.6.	**Failure of the power supply** The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations. Particular attention must be given to the following points: — the machinery must not start unexpectedly, — the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations, — the machinery must not be prevented from stopping if the command has already been given, L 157/40 EN Official Journal of the European Union 9.6.2006 — no moving part of the machinery or piece held by the machinery must fall or be ejected, — automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded, — the protective devices must remain fully effective or give a stop command.	NA		Covered by MDD Annex I, ER 12.1, 12.3, EN/IEC 60601-1, EN ISO 14971	-
1.3.	PROTECTION AGAINST MECHANICAL HAZARDS				
1.3.1.	**Risk of loss of stability** Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery. If the shape of the machinery itself or its intended installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions	NA		Covered by MDD Annex I, ER 9, 12.7.1 and EN/IEC 60601-1	-
1.3.2.	**Risk of break-up during operation** The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used. The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion. The instructions must indicate the type and frequency of inspections and maintenance required for safety reasons. They must, where appropriate, indicate the parts subject to wear and the criteria for replacement. Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations. Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by a rupture. Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to persons:	NA		Covered by MDD Annex I, ER 9, 12.7.1, 13.6 (d) and EN/IEC 60601-1	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	— when the workpiece comes into contact with the tool, the latter must have attained its normal working condition, — when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement must be coordinated.				
1.3.3.	**Risks due to falling or ejected objects** Precautions must be taken to prevent risks from falling or ejected objects.	NA		Covered by MDD Annex I, ER 9, 12 and EN/IEC 60601-1	-
1.3.4.	**Risks due to surfaces, edges or angles** Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.	NA		Covered by MDD Annex I, ER 9, 12.7.1 and EN/IEC 60601-1	-
1.3.5.	**Risks related to combined machinery** Where the machinery is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons. For this purpose, it must be possible to start and stop separately any elements that are not protected.	NA		No combined machinery used as described in this clause.	-
1.3.6.	**Risks related to variations in operating conditions** Where the machinery performs operations under different conditions of use, it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.	NA		Covered by MDD Annex I,ER 12.9	-
1.3.7.	**Risks related to moving parts** The moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices. All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools must, when appropriate, be provided to enable the equipment to be safely unblocked. The instructions and, where possible, a sign on the machinery shall identify these specific protective devices and how they are to be used.	NA		Covered by MDD Annex I, ER 9.2, 12.7.1, 13.6 and EN/IEC 60601-1 , and EN/IEC 60601-2-44	-
1.3.8.	**Choice of protection against risks arising from moving parts** Guards or protective devices designed to protect against risks arising from moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help to make the choice.				
1.3.8.1.	**Moving transmission parts** Guards designed to protect persons against the hazards generated by moving transmission parts must be: — either fixed guards as referred to in section 1.4.2.1, or — interlocking movable guards as referred to in section 1.4.2.2. Interlocking movable guards should be used where frequent access is envisaged.	NA		Covered by MDD Annex I, ER 9.2, 12.7.1 and EN/IEC 60601-1	-
1.3.8.2.	**Moving parts involved in the process** Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be: — either fixed guards as referred to in section 1.4.2.1, or	NA		Covered by MDD Annex I, ER 9.2, 12.7.1 and EN/IEC 60601-1	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	— interlocking movable guards as referred to in section 1.4.2.2, or — protective devices as referred to in section 1.4.3, or — a combination of the above. However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts must be fitted with: — fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and — adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.				
1.3.9.	**Risks of uncontrolled movements** When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.	NA		Covered by MDD Annex I, ER 12.7.1, EN/IEC 60601-1, and EN/IEC 60601-2-44	-
1.4.	REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES				
1.4.1.	**General requirements** Guards and protective devices must: — be of robust construction, — be securely held in place, — not give rise to any additional hazard, L 157/42 EN Official Journal of the European Union 9.6.2006 — not be easy to by-pass or render non-operational, — be located at an adequate distance from the danger zone, — cause minimum obstruction to the view of the production process, and — enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled. In addition, guards must, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery.	NA		Covered by MDD Annex I, ER 9.2, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-
1.4.2.	**Special requirements for guards**				
1.4.2. 1.	**Fixed guards** Fixed guards must be fixed by systems that can be opened or removed only with tools. Their fixing systems must remain attached to the guards or to the machinery when the guards are removed. Where possible, guards must be incapable of remaining in place without their fixings.	NA		Covered by MDD Annex I, ER 9.2, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-
1.4.2. 2.	**Interlocking movable guards** Interlocking movable guards must: — as far as possible remain attached to the machinery when open, — be designed and constructed in such a way that they can be adjusted only by means of an intentional action. Interlocking movable guards must be associated with an	NA		Covered by MDD Annex I, ER 9.2, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	interlocking device that: — prevents the start of hazardous machinery functions until they are closed and — gives a stop command whenever they are no longer closed. Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that: — prevents the start of hazardous machinery functions until the guard is closed and locked, and — keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased. Interlocking movable guards must be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery functions.				
1.4.2.3.	**Adjustable guards restricting access** Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must be: — adjustable manually or automatically, depending on the type of work involved, and — readily adjustable without the use of tools.	NA		Covered by MDD Annex I, ER 9.2, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-
1.4.3.	**Special requirements for protective devices** Protective devices must be designed and incorporated into the control system in such a way that: — moving parts cannot start up while they are within the operator's reach, 9.6.2006 EN Official Journal of the European Union L 157/43 — persons cannot reach moving parts while the parts are moving, and — the absence or failure of one of their components prevents starting or stops the moving parts. Protective devices must be adjustable only by means of an intentional action.	NA		Covered by MDD Annex I, ER 9.2, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-
1.5	RISKS DUE TO OTHER HAZARDS				
1.5.1	**Electricity supply** Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented. The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive.	NA		Covered in MDD Annex I ER 12 and EN/IEC 60601-1	-
1.5.2	**Static electricity** Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system	NA		Covered in MDD Annex I ER 9.2 and EN/IEC 60601-1	-
1.5.3	**Energy supply other than electricity** Where machinery is powered by source of energy other than electricity, it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.	NA		Covered in MDD Annex I ER 12 and EN/IEC 60601-1	-
1.5.4	**Errors of fitting** Errors likely to be made when fitting or refitting certain parts	NA		No fitting parts could lead to a source of risk.	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk. Where necessary, the instructions must give further information on these risks. Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.				
1.5.5	**Extreme temperatures** Steps must be taken to eliminate any risk of injury arising from contact with or proximity to machinery parts or materials at high or very low temperatures. The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material being ejected.	NA		Covered in MDD Annex I ER 9.2, 12.7.5 and EN/IEC 60601-1	-
1.5.6	**Fire** Machinery must be designed and constructed in such a way as to avoid any risk of fire or overheating posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.	NA		Covered in MDD Annex I ER 9.3 and EN/IEC 60601-1	-
1.5.7	**Explosion** Machinery must be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery. Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Community Directives.	NA		Covered in MDD Annex I ER 9.3 and EN/IEC 60601-1	-
1.5.8	**Noise** Machinery must be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source. The level of noise emission may be assessed with reference to comparative emission data for similar machinery.	NA		Covered in MDD Annex I ER 12.7.3 and EN/IEC 60601-1	-
1.5.9	**Vibrations** Machinery must be designed and constructed in such a way that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source. The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.	NA		Covered in MDD Annex I ER 12.7.2 and EN/IEC 60601-1	-
1.5.10	**Radiation** Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons. Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.	NA		Covered in MDD Annex I ER 11, ER 12.5 and EN/IEC 60601-1,and EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	Any functional non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.				
1.5.11	**External radiation** Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.	NA		Covered in MDD Annex I ER 9.2 and EN/IEC 60601-1	-
1.5.12	**Laser radiation** Where laser equipment is used, the following should be taken into account: — laser equipment on machinery must be designed and constructed in such a way as to prevent any accidental radiation, — laser equipment on machinery must be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health, — optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by laser radiation.	NA		Covered in MDD Annex I ER 11 and EN/IEC 60601-1	-
1.5.13	**Emissions of hazardous materials and substances** Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided. Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method. Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.	NA		Covered in MDD Annex I ER 7.1, 7.3, 7.5	-
1.5.14	**Risk of being trapped in a machine** Machinery must be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.	NA		Covered in MDD Annex I ER 9.2, 12.7 and EN/IEC 60601-1	-
1.5.15	**Risk of slipping, tripping or falling** Parts of the machinery where persons are liable to move about or stand must be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts. Where appropriate, these parts must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.	NA		No parts of machinery could lead to a source of risk	-
1.5.16	**Lightning** Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.	NA		Covered in MDD Annex I ER 9.2, 12.6 and EN/IEC 60601-1	-
1.6	MAINTENANCE				
1.6.1	**Machinery maintenance** Adjustment and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.	A	partially Covered in MDD Annex I ER 4, 13.6d, and EN/IEC 60601-1	EN/IEC 60601-1 test report Risk management report	OK

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	If one or more of the above conditions cannot be satisfied for technical reasons, measures must be taken to ensure that these operations can be carried out safely (see section 1.2.5). In the case of automated machinery and, where necessary, other machinery, a connecting device for mounting diagnostic fault-finding equipment must be provided. Automated machinery components which have to be changed frequently must be capable of being removed and replaced easily and safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.		EN ISO14971		
1.6.2	**Access to operating positions and servicing points** Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.	A	partially Covered in MDD Annex I ER 4, 13.6d, and EN/IEC 60601-1 EN ISO14971	EN/IEC 60601-1 test report Risk management report	OK
1.6.3	**Isolation of energy sources** Machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons. Isolators must also be capable of being locked where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off. In the case of machinery capable of being plugged into an electricity supply, removal of the plug is sufficient, provided that the operator can check from any of the points to which he has access that the plug remains removed. After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to persons. As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps must be taken to ensure operator safety.	A	Partially Covered by MDD Annex I, ER 12.2, ER13.6d, and EN/IEC 60601-1 EN ISO14971	EN/IEC 60601-1 test report Risk management report	OK
1.6.4	**Operator intervention** Machinery must be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it must be possible to carry it out easily and safely.	NA		Covered in MDD Annex I ER 12.7.4, 12.9, 13.6d	-
1.6.5	**Cleaning of internal parts** The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or preparations without entering them; any necessary unblocking must also be possible from the outside. If it is impossible to avoid entering the machinery, it must be designed and constructed in such a way as to allow cleaning to take place safely.	NA		Covered in MDD Annex I ER 7	-
1.7	INFORMATION				

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
1.7.1	**Information and warnings on the machinery** Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.	NA		Covered in MDD Annex I ER 11.4, 12.9, 13.1, 13.2	-
1.7.1.1	**Information and information devices** The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator. Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.	NA		Covered in MDD Annex I ER 11.4, 12.9, 13.1, 13.2, 13.6	-
1.7.1.2	**Warning devices** Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning. Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times. The requirements of the specific Community Directives concerning colours and safety signals must be complied with.	NA		Covered in MDD Annex I ER 2, 11.4, 12.3, 12.4, 13.2	-
1.7.2	**Warning of residual risks** Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.	NA		Covered in MDD Annex I ER 2, 11.4, 12.9,13	-
1.7.3	**Marking of machinery** All machinery must be marked visibly, legibly and indelibly with the following minimum particulars: — the business name and full address of the manufacturer and, where applicable, his authorised representative, — designation of the machinery, — the CE Marking (see Annex III), — designation of series or type, — serial number, if any, — the year of construction, that is the year in which the manufacturing process is completed. It is prohibited to pre-date or post-date the machinery when affixing the CE marking. Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly. Machinery must also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1. Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.	NA		Covered in MDD Annex I ER 13.3	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
1.7.4	**Instructions** All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service. The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions. 9.6.2006 EN Official Journal of the European Union L 157/47 By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand. The instructions must be drafted in accordance with the principles set out below.	NA		Covered in MDD Annex I ER 13	-
1.7.4.1	**General principles for the drafting of instructions** (a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative. (b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'. (c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof. (d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.	NA		Covered in MDD Annex I ER 13, EN/IEC 60601-1 and -1-6, EN 1041, EN ISO 14971	-
1.7.4.2	**Contents of the instructions** Each instruction manual must contain, where applicable, at least the following information: (a) the business name and full address of the manufacturer and of his authorised representative; (b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3); (c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature; (d) a general description of the machinery; (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning; (f) a description of the workstation(s) likely to be occupied by operators; (g) a description of the intended use of the machinery; (h) warnings concerning ways in which the machinery must not be used that experience has shown might	NA		Covered in MDD Annex I ER 13.6, EN/IEC 60601-1 and EN 1041,EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)	A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
occur; (i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted; (j) instructions relating to installation and assembly for reducing noise or vibration; (k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators; (l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted; (m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided; (n) the essential characteristics of tools which may be fitted to the machinery; (o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns; (p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately; (q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked; L 157/48 EN Official Journal of the European Union 9.6.2006 (r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed; (s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations; (t) the specifications of the spare parts to be used, when these affect the health and safety of operators; (u) the following information on airborne noise emissions: — the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated, — the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa), — the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A). These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced. In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission				

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	sound pressure levels at specified positions around the machinery may be indicated. Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described. Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated. Where specific Community Directives lay down other requirements for the measurement of sound pressure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply; (v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.				
1.7.4.3	**Sales literature** Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.	NA		Covered by MDD Article 1 g) and Annex I, ER 4, 13	-
2	SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OFMACHINERY Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).				
2.1	FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS				
2.1.1	**General** Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion. 9.6.2006 EN Official Journal of the European Union L 157/49 The following requirements must be observed: (a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used; (b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must: — be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings,	NA		Not relevant for medical devices	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	— be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum, — be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning; (c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a 'cleaning' position); (d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned; (e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.				
2.1.2	**Instructions** The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.	NA		Not relevant for medical devices	-
2.2	PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY				
2.2.1	**General** Portable hand-held and/or hand-guided machinery must: — depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions, — except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles, — present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible, — permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed. The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.	NA		Covered in MDD Annex I ER 9, 12	-
2.2.1.1	**Instructions** The instructions must give the following information concerning vibrations transmitted by portable handheld	NA		Covered in MDD Annex I ER 13.6	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	and hand-guided machinery: — the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s2. Where this value does not exceed 2,5 m/s2, this must be mentioned, — the uncertainty of measurement. These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced. If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery. The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.				
2.2.2	**Portable fixing and other impact machinery**				
2.2.2.1	**General** Portable fixing and other impact machinery must be designed and constructed in such a way that: — energy is transmitted to the impacted element by the intermediary component that does not leave the device, — an enabling device prevents impact unless the machinery is positioned correctly with adequate pressure on the base material, — involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact, — accidental triggering is prevented during handling or in case of shock, — loading and unloading operations can be carried out easily and safely. Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.	NA		Not relevant	-
2.2.2.2	**Instructions** The instructions must give the necessary information regarding: — the accessories and interchangeable equipment that can be used with the machinery, — the suitable fixing or other impacted elements to be used with the machinery, — where appropriate, the suitable cartridges to be used.	NA		Not relevant	-
2.3	MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS Machinery for working wood and materials with similar physical characteristics must comply with the following requirements: (a) the machinery must be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter must be sufficiently stable during the work and must not impede the movement of the piece; (b) where the machinery is likely to be used in conditions involving the risk of ejection of work pieces or	NA		Not relevant	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons; (c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down; (d) where the tool is incorporated into a non-fully automated machine, the latter must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.				
3	**SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY** Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).				
3.1	GENERAL				
3.1.1	**Definitions** (a) 'Machinery presenting hazards due to its mobility' means — machinery the operation of which requires either mobility while working, or continuous or semicontinuous movement between a succession of fixed working locations, or — machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another. (b) 'Driver' means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.	A	-	Defined terms necessary for the understanding	OK
3.2	WORK POSITIONS				
3.2.1	**Driving position** Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision. Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks. The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.	NA		Covered in MDD Annex I ER 2, 4, 9	-
3.2.2	**Seating** Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, their seats must be designed or equipped with a restraint system so as to keep the persons in	NA		Not relevant	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.				
3.2.3	**Positions for other persons** If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions must be provided which enable them to be transported or to work on it without risk. The second and third paragraphs of section 3.2.1 also apply to the places provided for persons other than the driver.	NA		Covered in MDD Annex I ER 2, 4, 9	-
3.3	CONTROL SYSTEMS If necessary, steps must be taken to prevent unauthorised use of controls. In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit. The remote control system must be designed and constructed in such a way as to affect only: — the machinery in question, — the functions in question. Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.	NA		Covered in MDD Annex I ER 2, 4, 9, 12.9 and EN/IEC 60601-1, EN ISO 14971	-
3.3.1	**Control devices** The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely. Where there are pedals, they must be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They must have a slip-resistant surface and be easy to clean. Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with preset positions, must return to the neutral position as soon as they are released by the operator. In the case of wheeled machinery, the steering system must be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels. Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving. The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.	NA		Covered in MDD Annex I ER 2, 4, 9, 12.9 and EN/IEC 60601-1,EN ISO 14971	-
3.3.2	**Starting/moving** All travel movements of self-propelled machinery with a	NA		Covered in MDD Annex I ER 2, 4, 9 and EN/IEC 60601-1,	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	ride-on driver must be possible only if the driver is at the controls. Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement. This also applies to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary. Where it does not give rise to other risks, movement of the machinery must depend on safe positioning of the aforementioned parts. It must not be possible for unintentional movement of the machinery to occur while the engine is being started.			EN ISO 14971	
3.3.3	**Travelling function** Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for. The driver must be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device must be provided for slowing down and stopping. Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, provided that it is purely mechanical. Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations: — if the driver loses control, — if it receives a stop signal, — if a fault is detected in a safety-related part of the system, — if no validation signal is detected within a specified time. Section 1.2.4 does not apply to the travelling function	NA		Covered in MDD Annex I ER 2, 4, 9 and EN ISO 14971	-
3.3.4	**Movement of pedestrian-controlled machinery** Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control device by the driver. In particular, it must not be possible for movement to occur while the engine is being started. The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular: — crushing, — injury from rotating tools. The speed of travel of the machinery must be compatible with the pace of a driver on foot. In the case of machinery on which a rotary tool may be fitted,	NA		Covered in MDD Annex I ER 2, 4, 9 and EN/IEC 60601-1, EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	it must not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.				
3.3.5	**Control circuit failure** A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.	NA		Covered in MDD Annex I ER 2, 4, 9 and EN/IEC 60601-1, EN ISO 14971	-
3.4	PROTECTION AGAINST MECHANICAL HAZARDS				
3.4.1	**Uncontrolled movements** Machinery must be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.	NA		Covered in MDD Annex I ER 2, 4, 9, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-
3.4.2	**Moving transmission parts** By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.	NA		Covered in MDD Annex I ER 2, 4, 9, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-
3.4.3	**Roll-over and tip-over** Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk. This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume. In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.	NA		Covered in MDD Annex I ER 2, 4, 9 and EN ISO 14971	-
3.4.4	**Falling objects** Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure. This structure must be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume. In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.	NA		Not relevant	-
3.4.5	**Means of access** Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist	A	Partially covered in MDD Annex I ER 2, 4, 9 and EN/IEC 60601-1, EN ISO 14971	EN/IEC 60601-1 test report Risk management report	OK

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	access.				
3.4.6	**Towing devices** All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use. Insofar as the tow bar load so requires, such machinery must be equipped with a support with a bearing surface suited to the load and the ground.	NA		Not relevant	-
3.4.7	**Transmission of power between self-propelled machinery (or tractor) and recipient machinery** Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length. On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection. It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving. On the recipient machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery. Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device must be marked accordingly. All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery. The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints. If means of access to working positions are provided near to the removable mechanical transmission device, they must be designed and constructed in such a way that the shaft guards cannot be used as steps, unlessdesigned and constructed for that purpose.	NA		Not relevant	-
3.5	PROTECTION AGAINST OTHER HAZARDS				

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
3.5.1	**Batteries** The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of vapours in places occupied by operators. Machinery must be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.				O K
3.5.2	**Fire** Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits: — either allow easily accessible fire extinguishers to be fitted, or — be provided with built-in extinguisher systems.				O K
3.5.3	**Emissions of hazardous substances** The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.				O K
3.6	INFORMATION AND INDICATIONS				
3.6.1	**Signs, signals and warnings** All machinery must have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible. Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment: — an acoustic warning device to alert persons, — a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery intended solely for underground working and having no electrical power, — where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals. Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver. Machinery must be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator. Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be	NA		Covered in MDD Annex I ER 2, 4, 9, 13 and EN/IEC 60601-1, EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	provided to warn against approaching the machinery while it is working; the signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.				
3.6.2	**Marking** The following must be shown legibly and indelibly on all machinery: — nominal power expressed in kilowatts (kW), — mass of the most usual configuration, in kilograms (kg); and, where appropriate: — maximum drawbar pull provided for at the coupling hook, in Newtons (N), — maximum vertical load provided for on the coupling hook, in Newtons (N).	A	EN/IEC 60601-1	EN/IEC 60601-1 test report User manual	OK
3.6.3	**Instructions**				
3.6.3.1	**Vibrations** The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body: — the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s2. Where this value does not exceed 2,5 m/s2, this must be mentioned, — the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s2. Where this value does not exceed 0,5 m/s2, this must be mentioned, — the uncertainty of measurement. These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced. L 157/56 EN Official Journal of the European Union 9.6.2006 Where harmonised standards are not applied, the vibration must be measured using the most appropriate measurement code for the machinery concerned. The operating conditions during measurement and the measurement codes used must be described.	NA		Covered in MDD Annex I ER 9, 12.7.2, 13 and EN/IEC 60601-1, EN ISO 14971	-
3.6.3.2	**Multiple uses** The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safe assembly and use of the basic machinery and the interchangeable equipment that can be fitted.	NA		Covered in MDD Annex I ER 13.6 (c)	-
4	**SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS** Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).				
4.1	GENERAL				
4.1.1	**Definitions** (a) 'Lifting operation' means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level. (b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position	A		Defined terms necessary for the understanding	OK

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	is determined by fixed points. (c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer or his authorised representative up to which a component is able to hold it and the maximum working load marked on the component. (d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory. (e) 'Static test' means the test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred. (f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly. (g) 'Carrier' means a part of the machinery on or in which persons and/or goods are supported in order to be lifted.				
4.1.2	**Protection against mechanical hazards**				
4.1.2.1	**Risks due to lack of stability** Machinery must be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook. To that end, the manufacturer or his authorised representative must use the appropriate verification methods.	NA		Covered by MDD Annex I, ER 5, 9, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-
4.1.2.2	**Machinery running on guide rails and rail tracks** Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment. If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machinery from overturning.	NA		Covered by MDD Annex I, ER 2, 9, 12.7.7 and EN/IEC 60601-1,EN ISO 14971	-
4.1.2.3	**Mechanical strength** Machinery, lifting accessories and their components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement must also be satisfied during transport, assembly and dismantling. Machinery and lifting accessories must be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use. The materials used must be chosen on the basis of the intended working environments, with particular regard	NA		Covered by MDD Annex I, ER 4, 5, 7.1, 9, 12.7.1 and EN/IEC 60601-1, EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing. Machinery and lifting accessories must be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values: (a) manually-operated machinery and lifting accessories: 1,5; (b) other machinery: 1,25. Machinery must be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out under the least favourable conditions, as a general rule by combining the movements concerned.				
4.1.2.4	**Pulleys, drums, wheels, ropes and chains** Pulleys, drums and wheels must have a diameter commensurate with the size of the ropes or chains with which they can be fitted. Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off. Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use. Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5. Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4. In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.	NA		Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN/IEC 60601-1,EN ISO 14971	-
4.1.2.5	**Lifting accessories and their components** Lifting accessories and their components must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application. Moreover: (a) the working coefficient of wire-rope/rope-end combinations must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes must not comprise	NA		Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN/IEC 60601-1, EN ISO 14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	any splices or loops other than at their ends; (b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4; (c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling; (d) all metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4; (e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration; (f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.				
4.1.2.6	**Control of movements** Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe. (a) Machinery must be designed and constructed or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning. (b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machinery must be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided. (c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine. (d) It must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that way. (e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.	NA		Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN/IEC 60601-1, EN ISO 14971	-
4.1.2.	**Movements of loads during handling**	NA		Covered by MDD Annex I, ER 2, 4, 9, 12.7.1 and EN/IEC	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
7	The operating position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard. Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.			60601-1, EN ISO 14971	
4.1.2.8	**Machinery serving fixed landings**				
4.1.2.8.1	Movements of the carrier The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.	NA		Not relevant	-
4.1.2.8.2	Access to the carrier Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded. The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.	NA		Not relevant	-
4.1.2.8.3	Risks due to contact with the moving carrier Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone must be rendered inaccessible during normal operation. When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.	NA		Not relevant	-
4.1.2.8.4	Risk due to the load falling off the carrier Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.	NA		Not relevant	-
4.1.2.8.5	Landings Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented. Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents: — hazardous movements of the carrier until the guards are closed and locked, — hazardous opening of a guard until the carrier has stopped at the corresponding landing.	NA		Not relevant	-
4.1.3	**Fitness for purpose** When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer	NA			-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	or his authorised representative must ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely. The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service. Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.				
4.2	REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT				
4.2.1	**Control of movements** Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.	NA		Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN/IEC 60601-1,EN ISO 14971 and EN 60601-2-44	-
4.2.2	**Loading control** Machinery with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements in the event: — of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or — of the overturning moment being exceeded.	NA		Not relevant	-
4.2.3	**Installations guided by ropes** Rope carriers, tractors or tractor carriers must be held by counterweights or by a device allowing permanent control of the tension.	NA		Not relevant	-
4.3	INFORMATION AND MARKINGS				
4.3.1	**Chains, ropes and webbing** Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorised representative and the identifying reference of the relevant certificate. The certificate mentioned above must show at least the following information: (a) the name and address of the manufacturer and, if appropriate, his authorised representative; (b) a description of the chain or rope which includes: — its nominal size, — its construction, — the material from which it is made, and — any special metallurgical treatment applied to the material; (c) the test method used; (d) the maximum load to which the chain or rope should be	NA		Covered by MDD Annex I, ER 13.3, 13.5	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	subjected in service. A range of values may be given on the basis of the intended applications.				
4.3.2	**Lifting accessories** Lifting accessories must show the following particulars: — identification of the material where this information is needed for safe use, — the maximum working load. In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or other equivalent means and securely affixed to the accessory. The particulars must be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.	NA		Covered by MDD Annex I, ER 13.3, 13.5	-
4.3.3	**Lifting machinery** The maximum working load must be prominently marked on the machinery. This marking must be legible, indelible and in an un-coded form. Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration. Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.	NA		Covered by MDD Annex I, ER 13.3, 13.5	-
4..4	INSTRUCTIONS				
4.4.1	**Lifting accessories** Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars: (a) the intended use; (b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e)); (c) instructions for assembly, use and maintenance; (d) the static test coefficient used.	NA		Covered by MDD Annex I, ER 13.5, 13.6	-
4.4.2	**Lifting machinery** Lifting machinery must be accompanied by instructions containing information on: (a) the technical characteristics of the machinery, and in particular: — the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3, — the reactions at the supports or anchors and, where appropriate, characteristics of the tracks, — where appropriate, the definition and the means of installation of the ballast; (b) the contents of the logbook, if the latter is not supplied with the machinery; (c) advice for use, particularly to offset the lack of direct vision of the load by the operator; (d) where appropriate, a test report detailing the static and	NA		Covered by MDD Annex I, ER 13.5, 13.6	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	dynamic tests carried out by or for the manufacturer or his authorised representative; (e) for machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.				
5	**SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK** Machinery intended for underground work must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).				
5.1	RISKS DUE TO LACK OF STABILITY Powered roof supports must be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.	NA		not relevant for medical devices	-
5.2	MOVEMENT Powered roof supports must allow for unhindered movement of persons.	NA		not relevant for medical devices	-
5.3	CONTROL DEVICES The accelerator and brake controls for movement of machinery running on rails must be hand-operated. However, enabling devices may be foot-operated. The control devices of powered roof supports must be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.	NA		not relevant for medical devices	-
5.4	STOPPING Self-propelled machinery running on rails for use in underground work must be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement	NA		not relevant for medical devices	-
5.5	FIRE The second indent of section 3.5.2 is mandatory in respect of machinery which comprises highly flammable parts. The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires. Machinery with internal combustion engines for use in underground workings must be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin	NA		not relevant for medical devices	-
5.6	EXHAUST EMISSIONS Exhaust emissions from internal combustion engines must not be discharged upwards.	NA		not relevant for medical devices	-
6	**SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS**				

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
6.1	GENERAL				
6.1.1	**Mechanical strength** The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load. The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling. If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.	NA		Covered in MDD Annex I ER 9, 12.7.1 and EN/IEC 60601-1, EN ISO 14971	-
6.1.2	**Loading control for machinery moved by power other than human strength** The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.	NA		Not relevant	-
6.2	CONTROL DEVICES Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier. In operation, those control devices must override any other devices controlling the same movement with the exception of emergency stop devices. The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.	NA		Covered by MDD Annex I ER 12.7 and EN/IEC 60601-1, EN ISO14971, and EN 60601-2-44	-
6.3	RISKS TO PERSONS IN OR ON THE CARRIER				
6.3.1	**Risks due to movements of the carrier** Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.	NA		Covered by MDD Annex I ER 2, 9.2, 12.7 and EN ISO14971	-
6.3.2	**Risk of persons falling from the carrier** The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving. Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements. 9.6.2006 EN Official Journal of the European Union L 157/63 If the measures referred to in section 1.5.15 are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points must be strong enough for the use of personal protective equipment	NA		Covered by MDD Annex I ER 2, 9.2, 12.7 and EN ISO14971	-

Essential Health and Safety Requirements acc. to Annex I of the MD (2006/42/EC)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation(test reports, protocols, literature or reason for nonapplicability)	Ok / Fail
	against falls from a height. Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.				
6.3.3	**Risk due to objects falling on the carrier** Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.	NA		Not relevant	-
6.4	MACHINERY SERVING FIXED LANDINGS				
6.4.1	**Risks to persons in or on the carrier** The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier. The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed. The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.	NA		not relevant	-
6.4.2	**Controls at landings** Controls, other than those for emergency use, at landings must not initiate movements of the carrier when: — the control devices in the carrier are being operated, — the carrier is not at a landing.	NA		not relevant	-
6.4.3	**Access to the carrier** The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons tobe lifted.	NA		not relevant	-
6.5	MARKINGS The carrier must bear the information necessary to ensure safety including: — the number of persons permitted on the carrier, — the maximum working load.	NA		Covered by MDD Annex I, ER 13.3	-

History Records

Version	Author	Change Summary	Effective Date
1.0	Wang Guan	First release	2017-11-1
2.0	Liang Tiecheng	1. Update the template 2. Appendix2-List of Referenced Documents, EN/IEC report updated	2019-4-30
3.0	Liang Tiecheng	1. Update the template 2. Appendix1-List of Referenced Documents updated	2021-5-26

Appendix 1 - List of Referenced Documents

Deliverables	Title	Revision #.	Date:
NPD-CT-0428	NeuViz Prime User Manual	E	2020-12
NPS-CT-0321E	NeuViz Prime Product Information Guide	B	2020-5
NPD-CT-0966	Label manual	2.0	2017-7-31
253103-70105342	EN/IEC 60601-1 test report	-	2017-03-27
253103-70102397	EN/IEC 60601-1-2 test report	-	2018-12-15
253103-70105342	EN/IEC 60601-1-3 test report	-	2017-03-27
253103-70105342	EN/IEC 60601-1-6 test report	-	2017-03-27
GTC-DTT-0598-16	EN/IEC 60601-2-28 test report	-	2019-9-9
253103-70105342	EN/IEC 60601-2-44 test report	-	2017-03-27
253103-70105342	EN/IEC 62366 test report	-	2017-03-27
253103-70105342	EN/IEC 62304 test report	-	2017-03-27
N13-CT02P-DR1500	NeuViz Prime Risk management plan	6.0	2020-8-11
N13-CT02P-DR1506	NeuViz Prime Risk Management report	7.4	2021-3-10
N13-CT02P-DV2406	Clinical Evaluation Report	1.0	2017-9-30
Q5 098883 0004 Rev.00	Certificate of compliance EN ISO 13485: 2016	-	2021-4-10
N13-CT02P-DD1512	Biocompatibility Assessment report	4.0	2020-4-24
N13-CT02P-DV2037	Product verification report	1.0	2016-8-12
N13-CT02P-DP1621	Product validation plan	1.0	2018-3-12
N13-CT02P-DV3285	Product validation report	1.0	2018-3-15