



Essential Requirements

etkon iDent Custom-made Dental Restorative Devices

According to 93/42/EEC annex I as amended by 2007/47/EC

Straumann's CAD (Computer Aided Design) software CARES Visual has built-in parameter checks to assure that a dental restorative device basically meets the generally applicable requirements. However, etkon GmbH cannot assess a particular patient situation for suitability of a custom-made device.

It is the practitioner's responsibility to use the device in accordance with the IFU and to determine if the device fits the individual patient situation.

The below list indicates which Essential Requirements (acc. to annex I of Council Directive 93/42/EEC) are met by etkon measures and which fall under the customer's responsibility.

Requirement	Requirement met/not met/comment
<i>ANNEX I</i>	
ESSENTIAL REQUIREMENTS	
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 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:	customer's/ordering party's responsibility
— 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).	yes
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),	customer's/ordering party's responsibility
— where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	customer's/ordering party's responsibility
— inform users of the residual risks due to any shortcomings of the protection measures adopted.	customer's/ordering party's responsibility
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.	customer's/ordering party's responsibility
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 conditions 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.	customer's/ordering party's responsibility
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.	yes
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	customer's/ordering party's responsibility
6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	yes
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 I on the 'General requirements'. Particular attention must be paid to:	
— the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	yes
— the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,	yes
— where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	yes
7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	yes



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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;	yes
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 these products and that their performance is maintained in accordance with the intended use.	not applicable Device is not intended to administer medicinal products.
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 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 (EMA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (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 EMA 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 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 EMA, 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 EMA 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.	not applicable Device does not contain a substance that could be considered medicinal product.
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.	yes
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 (1).	not applicable Device does not contain components which are known to cause carcinogenic, mutagenic or reprotoxic effects.
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.	not applicable Device is not intended to administer and/or remove medicines, body liquids or other substances to or from the body ... Device does not contain 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.	not applicable Device is not intended to administer and/or remove medicines, body liquids or other substances to or from the body ... Device does not contain phthalates.
7.6. 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.	yes



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8. Infection and microbial contamination	
8.1. The devices and 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, minimize contamination of the device by the patient or vice versa during use.	yes
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.	not applicable Device does not contain material of animal origin.
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 that 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.	not applicable Device is not provided sterile.
8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	not applicable Device is not provided sterile.
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	yes
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 sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	yes
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.	yes
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 performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	yes
9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:	
— the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,	customer's/ordering party's responsibility
— risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,	yes
— the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,	yes
— risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	yes
9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	not applicable No risk of fire or explosion is associated with device.
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.	not applicable Device is not with measuring function.
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.	not applicable Device is not with measuring function.
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 (1).	not applicable Device is not with measuring function.
11. Protection against radiation	
11.1. General	
11.1.1. Devices shall be designed and manufactured in such a way 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.	not applicable Device does not emit radiation. Device is not susceptible to electromagnetic radiation. Device characteristics do not change under electromagnetic radiation. Device does not alter significantly electromagnetic fields.



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11.2. Intended radiation	
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 reproducibility and tolerance of relevant variable parameters.	not applicable Device does not emit radiation.
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.	not applicable Device does not emit radiation.
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 reduced as far as possible.	not applicable Device does not emit radiation.
11.4. Instructions	
11.4.1. 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.	not applicable Device does not emit radiation.
11.5. Ionizing radiation	
11.5.1. Devices intended to emit ionizing 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 use.	not applicable Device is not intended to emit ionizing radiation.
11.5.2. Devices emitting ionizing 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 minimizing radiation exposure of the patient and user.	not applicable Device does not emit ionizing radiation.
11.5.3. Devices emitting ionizing 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 radiation.	not applicable Device does not emit ionizing radiation.
12. Requirements for medical devices connected to or equipped with an energy source	
12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the 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.	not applicable Device does not incorporate electronic programmable systems.
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.	not applicable Device does not contain software.
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.	not applicable Device is not connected to or equipped with energy source.
12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	not applicable Device is not connected to or equipped with an energy source.
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.	not applicable Device does not monitor patient parameters.
12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	not applicable Device does not create magnetic field.
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 the devices are installed correctly.	not applicable Device is not connected to or equipped with an energy source.
12.7. Protection against mechanical and thermal risks	
12.7.1. 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.	
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.	not applicable Device is not source of vibration.
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.	not applicable Device is not source of noise.
12.7.4. 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 minimize all possible risks.	not applicable No terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies.



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12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	not applicable Device does not attain potentially dangerous temperatures under normal use.
<i>12.8. Protection against the risks posed to the patient by energy supplies or substances</i>	
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.	not applicable Device does not supply the patient with energy or substances.
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.	not applicable Device does not supply the patient with energy or substances.
<i>12.9. The function of the controls and indicators must be clearly specified on the devices.</i>	
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.	not applicable Device does not bear instructions.
13. Information supplied by the manufacturer	
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 instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	yes
13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	yes
<i>13.3. The label must bear the following particulars:</i>	
(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 authorised representative where the manufacturer does not have a registered place of business in the Community;	yes
(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;	yes
(c) where appropriate, the word 'STERILE';	not applicable Device is not provided sterile.
(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	yes
(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	not applicable Expiry date is not appropriate for a custom-made device.
(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;	yes
(g) if the device is custom-made, the words 'custom-made device';	yes
(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	not applicable Device is not intended for clinical investigations.
(i) any special storage and/or handling conditions;	not applicable No special storage and/or handling conditions
(j) any special operating instructions;	not applicable no special operating instructions
(k) any warnings and/or precautions to take;	yes
(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;	not applicable Not an active device.
(m) where applicable, method of sterilization;	not applicable Not delivered sterile.
(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	not applicable Not a device within the meaning of Article 1(4a).
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.	yes
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.	yes



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13.6. Where appropriate, the instructions for use must contain the following particulars:	
(a) the details referred to in Section 13.3, with the exception of (d) and (e);	yes
(b) the performances referred to in Section 3 and any undesirable side effects;	yes
(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;	yes
(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;	yes
(e) where appropriate, information to avoid certain risks in connection with implantation of the device;	yes
(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	yes
(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	not applicable Not delivered sterile.
(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.	not applicable Device is for single use only.
Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.	not applicable Device is not intended to be sterilized.
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;	not applicable Device is for single use only. Device design is patient specific.
(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	yes
(j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	not applicable Device does not emit radiation.
The instructions 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;	yes
(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.;	yes
(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;	not applicable Device is not intended to administer a medicinal product.
(n) precautions to be taken against any special, unusual risks related to the disposal of the device;	not applicable No unusual risks associated with disposal of device.
(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	not applicable No medicinal substances or human blood derivatives are incorporated in the device.
(p) degree of accuracy claimed for devices with a measuring function;	not applicable Device is not with measuring function.
(q) date of issue or the latest revision of the instructions for use.	yes