Design & Development Compliance

3 Biological Hazards	Report
(a) The device must be designed with particular attention to the choice of materials used, particularly as regards toxicity and where appropriate, flammability.	N/A } Non Medical
(b) The device must be designed with particular attention to the compatibility between materials used and biological tissues, cells and fluids, taking account of the intended purpose of the device.	N/A
(c) The device must be designed in such a way as to minimise the risks posed by the unintentional ingress of substances into the device taking into account the device and the environment in which it is intended to be used.	→ Splash proof ?
(d) The device must be designed with particular attention to reducing to a minimum the risks posed by substances leaking from the device.	N/A Electronic 1 9v Batt.

4 Material Physical Properties	Report
(a) The materials used shall be appropriate for the intended purpose, taking account of strength, elasticity, melting point, porosity, conductance etc.	? Drop test etc
(b) The surface finishes shall be suitable for the intended purpose of the device.	
(c) The materials selected shall be appropriate for any sterilisation / disinfection / cleaning requirements.	Cleaning Soap & Water
(d) The characteristics and performance 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 when the device is subjected to the stresses which can occur during the normal conditions of use. i.e. ageing and corrosion.	N/A Non Medical

5 User Information	Report
(a) Each device must be accompanied by the information needed to use it safely, taking account of the training and knowledge of the potential users. This information comprises details on the label and the data in the instructions for use.	
(b) Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards.	
The label must bear the following particulars: Identification of Viamed as the Manufacturer. If the device is custom made the words "Custom-made device"	N/A
The label or instructions must contain the following instructions where appropriate: • Any special storage or handling precautions • Any special operating instructions • Any warnings and/or precautions to be taken. • Where appropriate, the method of sterilisation.	

6 Contamination	Report
(a) The device must be designed in such a way as to eliminate or reduce as far as possible the risk on 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.	N/A Non Invasive. No Patient Contact
(b) Devices delivered in a sterile state must be packaged in a non-reusable pack and remain sterile under normal transport and storage conditions, until the protective packaging is damaged or opened.	Non Sterile
(c) Devices delivered in a sterile state must have been sterilised by an appropriate method.	NOT STERILE
(d) Devices that require sterilisation before use, but are supplied to the user in a non-sterile state, will be labelled to indicate this.	NOT STERILE
(e) The packaging for non-sterile devices must maintain the device cleanliness without deterioration, and minimise the risk of microbial contamination. The packaging system must be suitable, taking into account the method of sterilisation recommended.	NOT STERILE
7 Radiation	**Report**
(a) Devices must 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.	No Radiation
(b) 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 omission, 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 parameters.	
(c) Where devices are intended to emit potentially hazardous visible and/or invisible radiation, they must be fitted, where practicable, with visual displayed and/or audible warnings of such emissions.	
(d) Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emissions of unintended, stray or scattered radiation is reduced as far as possible.	
(e) 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 risk inherent in installation.	