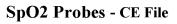


Design & Development Compliance

DESCRIPTION	JOB NUMBER
Pulse Oximeter Probes	960110

1. General	Report
(a) The solutions adopted for the design and construction of the devices must conform to safety principals to eliminate or reduce risks as far as possible (inherently safe design and construction). The device must be designed in such a way that, when used under the conditions and for the purpose intended, it will not compromise the safety of patients, or the safety and health of users or, where applicable, other persons.	IEC 601 Compatibility to original manufacturers probes
The device must be designed with particular attention to: • Electrical Safety • Moving Parts	Proven design
• Enclosures	No enclosure
Stability	N/A
Expelled Parts	No expelled parts
Vibration & Noise (b) Where modification of other manufactured devices is required, written approval will be sought from the manufacturer, otherwise concessionary status will be sought.	No noise or vibration
2. Environment	Report
(a) If the device is intended for use in combination with other devices or equipment, the whole combination, including connection system, must be made safe and must not impair the specified performance of the device.	Tested with original device
(b) The devices must be designed in such a way that they can be used safely with the materials, substances and gases with which they enter contact with during their normal use or during routine procedures.	N/A
(c) Accessible parts of the device (excluding parts or areas intended for supply or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	N/A
(d) Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances that could cause combustion.	N/A
(e) Devices must be designed and manufactured in such a way as to minimise the risks connected with environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration.	IEC 60601-1 & 60601-2
3. Biological Hazards	Report
(a) The device must be designed with particular attention to the	All materials compatible





appropriate, flammability.	
(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.	Sealed with silicone rubber
(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
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. (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.	
(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 nd corrosion.	
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.	Report Insert
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SpO2 Probes - CE File

(b) Devices delivered in a sterile s reusable pack and remain sterile und conditions, until the protective packaging		N/A
(c) Devices delivered in a sterile st an appropriate method.	tate must have been sterilised by	N/A
(d) Devices that require sterilisation the user in a non-sterile state, will be lab	n before use, but are supplied to belled to indicate this.	N/A
cleanliness without deterioration, and contamination. The packaging system account the method of sterilisation record	n must be suitable, taking into	N/A
7. Radiation		Report
(a) Devices must be designed and exposure of patients, users and othe reduced as far as possible, compatible not restricting the application of appropriand diagnostic purposes.	with the intended purpose, whilst	N/A
(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 emissions. 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.		N/A
(c) Where devices are intended to emit potentially hazardous visible and / or invisible radiation, they must be fitted, where practicable, with visual diplayed and / or audible warnings of such emissions.		N/A
(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,		N/A
(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.		N/A
Standards and Statutory Requirements appropriate at this stage	Rec	quirement
IEC 601		



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Final Design Tests Proposed	Acceptance Criteria for Tests
IEC 601 IEC 60601-1 IEC 60601-2 Test on OEM Tests on DL3000 Simulator	
Quotation Authorised by:	
Name: N/A	Date:
Drawings Enclosed: Yes () No (Not Applicable ()
Client Acceptance:	
Authorised by: N/A	
Position:	
Date:	
Order Number:	