Checklist of Compliance with Essential Standards of Medical Devices Directive 93/42EEC

Product	Nerve Stimulator	New product	No
Part Number	MS1000 & DBS	Existing Product	Yes
Description	Nerve stimulator	Introduced	1984
		Main Standard	None
		Class	11a

Ref	Essential Requirement	A/NA	Standard	Report
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 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.	A	None	Based on an existing product in use since 1984
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	None	Manufactured ail safe. i.e cannot be left switched on
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	None	
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.	A	None	
5	The devices must be designed, manufactured and packed in such a way that their characteristics & performances during their intended use will not be adversely affected during transport & storage taking account of the instructions and information provided by the manufacturer.	A		Carrying bag supplied as standard

Ref	Essential Requirement	A/NA	Standard	Report
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	A		
7	Chemical, physical and biological properties	N\A		
7.1	The devices must be designed & manufactured in such a way as to guarantee the characteristics & 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 & 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.	N\A		
7.2	The devices must be designed, manufactured & packed in such a way as to minimise the risk posed by contaminants & residues to the persons involved in the transport, storage and use of the devices & to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed & to the duration and frequency of exposure.	N/A		
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances & 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 & manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products & that their performance is maintained in accordance with intended use.	A		No Medicinal substances
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may he considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC.	N/A		No Medicinal substances
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.	N/A		No substances
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.	N/A		No substances
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, minimise contamination of the device by the patient or vice versa during use.	A		Uses standard disposable elctrodes
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls & surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals.	N/A		No animal tissues

	Processing, preservation, testing and handling of tissues, cells & substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses & other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.			
8.3	Devices delivered in a sterile state must be designed, manufactured & packed in a non-reusable pack &/or according to appropriate procedures to ensure that they are sterile when placed on the market & remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	N/A		Not sterile
8.4	Divices delivered in a sterile state must have been manufactured and sterilised by an appropiate ,validated method.	N/A		Not sterile
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e. g. environmental) conditions.	N/A		Not sterile
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.			Not sterile
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		Not sterile
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.	A		Stand alone device
9.2	Devices must be designed and manufactured in such a way as to remove or minimise as far as is possible:			
	- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,	N/A		No volume/presure
	- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure,temperature or variations in pressure and acceleration,	N/A		No electrical effects
	- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,	A		possible effect on pacemakers
	- 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.	N/A		None
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. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	N/A		
10	Devices with a measuring function	N/A		No measuring function
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and	N/A		No measuring function

	'exclusively for clinical investigation';			
i	any special storage and/or handling conditions;	N\A		Insert
i	any special operating instructions;	A		Insert
k	any warnings and/or precautions to take;	A		Insert
l	year of manufacrure for active devices other than those covered by (c). This indication may be included in the batch or serial number;	N\A		
	(m) where applicable, method of sterilization.	N\A		Not to be sterilised
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.	A		Insert
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	N/A		
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)&(c);			
b	the performances referred to in Section 3 and any undesirable side-effects;	A		Insert
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;	N\A		Stand alone equipment
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;	N\A		Not required
e	where appropriate information to avoid certain risks in connection with implantation of the device;	N\A		Not implanted
f	information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	A		Pacemakers
g	the necessary instructions in the event of damage of the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation;	N\A		Not 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 resrriction on the number of reuses. 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;	A		Information on insert
i	details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	N\A		
j	in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any	A		

	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 kperformance of the device;			
l	precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influence, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	N\A		No effect used only intermittantly
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\A		Does not deliver
n	precautions to be taken against any special, unusual risks related ro the disposal of the device;	N\A		No disposal hazard
o	medicinal substances incorporated into the device as an integral part in accordance with section 7.4;	N\A		No medicinal substances
	((p)degree of accuracy claimed for devices with a measuring function.	N\A		No accuracy
14	Where conformiry with the essential requirements must be based on clinical data, as in Section I (6), such data must be established in accordance with Annex X.	N/A		Not required