Microstim MkIII Essential Requirements 23 Sep 2015

Section: 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.

Standards Applied
EN ISO 14971:2012
EN 60601-1:2006
EN 60601-1:2006/A1:2013
EN 60601-1-2:2007
EN 60601-1-6:2010
EN 60601-1-10:2008
EN 60601-1-11:2010
EN 60601-2-10:2000
EN 60601-2-10:2000/A1:2001
ISO 14971:2007 BS EN ISO 15223-1:2012 ISO 13465

Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9360 Microstim Device Design Theory Stimulator Theory General
#9287 Microstim MkIII Risk analysis reports switches
#9268 Microstim MkIII Risk analysis reports Classification certificate - Rework Risk Assesment
#8100 Microstim Design Changes C4 mod V2.4
#8090 Microstim Design Changes DB2 Capacitor movement C6 & C& added
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#7435 Microstim MkIII Risk analysis reports 1gz Continuous
#3913 Microstim MkIII Design Input Device Design Theory No Display reasons
#3365 Microstim MkIII Design Changes #688 PCB REV0 UPDATE GERBER SPEC
#3361 Microstim MkIII Design Input Device Design Theory Technical Description of the Microsti1
#3358 Microstim MkIII Design Input Device Design Theory NJNH Stimulator Theory bGeneral
#3357 Microstim MkIII Design Input Device Design Theory
#3356 Microstim MkIII Design Input Device Design Theory Calculations_Microstim
#3295 Microstim MkIII Description of Device MS3TDV1
#3285 2004 Microstim MkIII Risk analysis reports
#3285 2004 Microstim MkIII Risk analysis reports
#1717 Microstim Design Input Device History Statement 2004
#1654 Microstim Design Changes MRI design File
#1021 Microstim EN ISO 14971:2001 Annex A

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Section: 1 i

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),

Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9287 Microstim MkIII Risk analysis reports switches
#9268 Microstim MkIII Risk analysis reports Classification certificate - Rework Risk Assesment
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#7435 Microstim MkIII Risk analysis reports 1gz Continuous
#3285 2004 Microstim MkIII Risk analysis reports
#3285 2004 Microstim MkIII Risk analysis reports
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Notes:
Hand held units - only the electrodes come into contact with the patient,Unit is light and if dropped on the patient there is no risk of harm.

Section: 1 ii

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).

Notes:
Only to be used by trained anaesthetists

Section: 2 i

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:

Standards Applied
EN 1041:2008
 ISO 14971:2007

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Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9287 Microstim MkIII Risk analysis reports switches
#9268 Microstim MkIII Risk analysis reports Classification certificate - Rework Risk Assesment
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#7435 Microstim MkIII Risk analysis reports 1gz Continuous
#3285 2004 Microstim MkIII Risk analysis reports
#3285 2004 Microstim MkIII Risk analysis reports
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Notes:
Parts of new standard added to new appendix A

Section: 2 ii

eliminate or reduce risks as far as possible (inherently safe design and construction),

Notes:
parts of new standard added to new Appendix A

Section: 2 iii

where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

Notes:
New parts added to Appendix A

Section: 2 iv

inform users of the residual risks due to any shortcomings of the protection measures adopted.

Notes:
new parts added to new appendix A

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Section: 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.

Supporting Document IDs
#15573 BS EN 60601-2-10:2015 Nerve Stimulators
#9346 Microstim MkIII Test Reports AML Apr 2009
#9153 Microstim MkIII Validation Y.06 Design Compliance_Microstim
#9152 Microstim Validation CE FILE Microstim MkIII Validation QC 30 Project Validation
#9027 Microstim MkIII Packaging Trials and validation Microstim Packaging Trials and validation
#9027 Microstim MkIII Packaging Trials and validation Microstim Packaging Trials and validation
#8527 2510000 Microstim DB3 Specifications
#8119 Microstim MkIII Test Reports 2009 batch test
#8054 Microstim MkIII Test Reports MkII graphs 2004 June 2
#3435 Microstim MkIII Test Reports Test Report of Microstim DB
#3434 Microstim MkIII Test Reports Sample Bursts
#3433 Microstim MkIII Test Reports Pre mod TX 050420
#3432 Microstim MkIII Test Reports DBIII Transformer Tests
#3428 Microstim MkIII Test Reports 2006 waveforms actual
#3427 Microstim MkIII Test Reports 688# Microstim DBS Mk3 SCH JAN 24
#3405 Microstim MkIII Validation 20 July 2007
#3320 Microstim MkIII Packaging Trials and validation white box
#3319 Microstim MkIII Packaging Trials and validation #688 paper packing
#1247 Microstim Packaging Trials and validation pictures b

Section: 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.

Supporting Document IDs
#15596 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Microstim info from papers
#15595 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Clinical evaluation Microstim
#15425 Microstim MkIII Risk analysis reports
#15301 Microstim MkIII Post Market Clinical Follow-up
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9287 Microstim MkIII Risk analysis reports switches
#9268 Microstim MkIII Risk analysis reports Classification certificate - Rework Risk Assesment
#8107 Microstim MkIII Clinical Trials
#8035 Microstim Pre-Clinical Trials Data
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#7435 Microstim MkIII Risk analysis reports 1gz Continuous
#3285 2004 Microstim MkIII Risk analysis reports

#3285 2004 Microstim MkIII Risk analysis reports
#1225 Microstim Clinical Trials
#1064 Microstim Product Life
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Notes:
new parts added to appendix A

Section: 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.

Supporting Document IDs
#9154 Microstim MkIII Design Reviews QC24 AML
#9027 Microstim MkIII Packaging Trials and validation Microstim Packaging Trials and validation
#9027 Microstim MkIII Packaging Trials and validation Microstim Packaging Trials and validation
#8052 Microstim MkIII Design Reviews QC24 case review 2005 May
#8049 Microstim MkIII Design Reviews QC24 2005 May QC24 2005 May
#8048 Microstim MkIII Design Reviews QC24 Tx output voltage
#7923 Microstim MkIII Design Reviews QC24 MicroStim LED and vlotage measurement on June,11,2005
#6969 Microstim MkIII Design Reviews QC24 New Layout SMT Apr 2009 Microstim MkIII Parts List
#3423 Microstim MkIII Design Reviews QC24 Pot & Knob
#3422 Microstim MkIII Design Reviews QC24 Microstim mods 3
#3421 Microstim MkIII Design Reviews QC24 Microstim mods 2
#3420 Microstim MkIII Design Reviews QC24 Microstim mods 1
#3418 Microstim MkIII Design Reviews QC24 Microstim Case II Comments
#3417 Microstim MkIII Design Reviews QC24 Comments on the Microstim Sample Case
#3416 Microstim MkIII Design Reviews QC24 Meeting Viamed 6Sep05
#3415 Microstim MkIII Design Reviews QC24 Knob problem
#3414 Microstim MkIII Design Reviews QC24 Design review with John Lamb and Peter Anderson on the 16th March 2005
#3410 Microstim MkIII Design Reviews QC24 2005 Jan 05
#3409 Microstim MkIII Design Reviews QC24 2005 Apr 14
#3408 Microstim MkIII Design Reviews QC24 2005 07 13
#3320 Microstim MkIII Packaging Trials and validation white box
#3319 Microstim MkIII Packaging Trials and validation #688 paper packing
#1247 Microstim Packaging Trials and validation pictures b

Microstim MkIII Essential Requirements 23 Sep 2015

Section: 6

Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

Supporting Document IDs
#15596 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Microstim info from papers
#15595 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Clinical evaluation Microstim
#15425 Microstim MkIII Risk analysis reports
#15301 Microstim MkIII Post Market Clinical Follow-up
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9287 Microstim MkIII Risk analysis reports switches
#9268 Microstim MkIII Risk analysis reports Classification certificate - Rework Risk Assesment
#8107 Microstim MkIII Clinical Trials
#8035 Microstim Pre-Clinical Trials Data
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#7435 Microstim MkIII Risk analysis reports 1gz Continuous
#3285 2004 Microstim MkIII Risk analysis reports
#3285 2004 Microstim MkIII Risk analysis reports
#1225 Microstim Clinical Trials
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Notes:
new parts added to new appendix A

Section: 6 ii

Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.

Supporting Document IDs
#15596 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Microstim info from papers
#15595 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Clinical evaluation Microstim
#15301 Microstim MkIII Post Market Clinical Follow-up
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#8107 Microstim MkIII Clinical Trials
#1225 Microstim Clinical Trials

Microstim MkIII Essential Requirements 23 Sep 2015

Section: 7.1 i

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’.

Supporting Document IDs
#9157 Microstim Bio-compatibility

Notes:
General statement on flammability of components NB All electronic components are used within there specification. Need flammability report on plastic.

Section: 7.1 ii

the choice of materials used, particularly as regards toxicity and, where appropriate, flammability

Section: 7.1 ii

the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,

Supporting Document IDs
#9157 Microstim Bio-compatibility

Section: 7.1 iii

where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.

Microstim MkIII Essential Requirements 23 Sep 2015

Section: 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

Supporting Document IDs
#15596 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Microstim info from papers
#15595 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Clinical evaluation Microstim
#15425 Microstim MkIII Risk analysis reports
#15301 Microstim MkIII Post Market Clinical Follow-up
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9287 Microstim MkIII Risk analysis reports switches
#9268 Microstim MkIII Risk analysis reports Classification certificate - Rework Risk Assesment
#9027 Microstim MkIII Packaging Trials and validation Microstim Packaging Trials and validation
#9027 Microstim MkIII Packaging Trials and validation Microstim Packaging Trials and validation
#8035 Microstim Pre-Clinical Trials Data
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#7435 Microstim MkIII Risk analysis reports 1gz Continuous
#3320 Microstim MkIII Packaging Trials and validation white box
#3319 Microstim MkIII Packaging Trials and validation #688 paper packing
#3285 2004 Microstim MkIII Risk analysis reports
#3285 2004 Microstim MkIII Risk analysis reports
#1247 Microstim Packaging Trials and validation pictures b
#1225 Microstim Clinical Trials
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Section: 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 these products and that their performance is maintained in accordance with the intended use.

Supporting Document IDs
#15596 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Microstim info from papers
#15595 Microstim MkIII Clinical Trials Reports Reviews and Post Market Surveillance Clinical evaluation Microstim
#15301 Microstim MkIII Post Market Clinical Follow-up
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#8107 Microstim MkIII Clinical Trials
#8035 Microstim Pre-Clinical Trials Data
#1225 Microstim Clinical Trials

Section: 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 (EMEA) 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 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 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.

Supporting Document IDs
#13136 Medicinal Substances None

Microstim MkIII Essential Requirements 23 Sep 2015

Section: 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 (1).
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.

Supporting Document IDs
#13136 Medicinal Substances None
#9458 Leakage and Liquid damage BLANK

Notes:
E6 needs date and signatureZ8 needs date

Section: 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.

Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9287 Microstim MkIII Risk analysis reports switches
#9268 Microstim MkIII Risk analysis reports Classification certificate - Rework Risk Assesment
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#7435 Microstim MkIII Risk analysis reports 1gz Continuous
#3417 Microstim MkIII Design Reviews QC24 Comments on the Microstim Sample Case
#3416 Microstim MkIII Design Reviews QC24 Meeting Viamed 6Sep05
#3285 2004 Microstim MkIII Risk analysis reports
#3285 2004 Microstim MkIII Risk analysis reports
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Microstim MkIII Essential Requirements 23 Sep 2015

Notes:
new parts added to appendix A

Section: 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.

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 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.

Supporting Document IDs
#13135 No Animal Tissues No Animal Substances

Notes:
NB may need date

Section: 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.

Microstim MkIII Essential Requirements 23 Sep 2015

Supporting Document IDs
#9062 Microstim MkIII Sterilisation Microstim Sterilisation

Section: 8.4

Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.

Supporting Document IDs
#9062 Microstim MkIII Sterilisation Microstim Sterilisation

Section: 8.5

Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.

Supporting Document IDs
#9062 Microstim MkIII Sterilisation Microstim Sterilisation

Section: 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.

Supporting Document IDs
#9027 Microstim MkIII Packaging Trials and validation Microstim Packaging Trials and validation
#9027 Microstim MkIII Packaging Trials and validation Microstim Packaging Trials and validation
#3320 Microstim MkIII Packaging Trials and validation white box
#3319 Microstim MkIII Packaging Trials and validation #688 paper packing
#1247 Microstim Packaging Trials and validation pictures b

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Section: 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.

Supporting Document IDs
#9462 Microstim MkIII Labels 250001 box label
#9062 Microstim MkIII Sterilisation Microstim Sterilisation
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 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

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#3280 Microstim MkIII EMC rationale
#1771 Microstim Design Input OEM Files 2003
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 9.2

Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:

Standards Applied
EN ISO 14971:2012
 EN 60601-1:2006/A1:2013
 EN 60601-2-10:2000/A1:2001

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Supporting Document IDs
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#1021 Microstim EN ISO 14971:2001 Annex A
#1017 Microstim EMC rationale

Notes:
new parts added to new appendix A 60601-2- xx are specific standards to specifica equipment to be used with 600601 the general standard

Section: 9.2 i

the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,

Notes:
I would leave this as 9.2

Section: 9.2 ii

risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,

Notes:
I would leave this 9.2

Section: 9.2 iii

the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,

Notes:
I would leave this 9.2

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Section: 9.2 iv

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.

Notes:
I would leave this 9.2

Section: 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.

Section: 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.

Supporting Document IDs
#15573 BS EN 60601-2-10:2015 Nerve Stimulators
#15301 Microstim MkIII Post Market Clinical Follow-up
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9407 Microstim MkIII Design Input Device History Y.01 Design History_Microstim DB
#9156 Microstim MkIII Design Input Device History Manufacturing constraints on the Microstim DB mkIII
#8527 2510000 Microstim DB3 Specifications
#8107 Microstim MkIII Clinical Trials
#8035 Microstim Pre-Clinical Trials Data
#3435 Microstim MkIII Test Reports Test Report of Microstim DB
#3428 Microstim MkIII Test Reports 2006 waveforms actual
#3354 Microstim MkIII Design Input Device History Manufacturing Detail MS3MANV1
#3351 Microstim MkIII Design Input Device History Design Goals MS3DGV1

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Section: 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.

Section: 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).

Supporting Document IDs
#15573 BS EN 60601-2-10:2015 Nerve Stimulators
#8527 2510000 Microstim DB3 Specifications

Notes:
M3 Specification needs updating

Section: 11.1

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.

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 11.2

Intended radiation

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

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Section: 11.2 i

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.

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 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

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 11.3

Unintended radiation

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 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.

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Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 11.4

Instructions

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 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.

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 11.5

Ionizing radiation

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 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.

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Section: 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.

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 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.

Supporting Document IDs
#9456 Generic CE File Attached to All Ionising Radiation None

Section: 12

Requirements for medical devices connected to or equipped with an energy source

Supporting Document IDs
#3438 Microstim MkIII Software 28_01_1996

Section: 12.1 i

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.

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Section: 12.1 ii

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

Supporting Document IDs
#3438 Microstim MkIII Software 28_01_1996
#1064 Microstim Product Life

Section: 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.

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9150 Microstim MkIII Description of Device Technical
#3295 Microstim MkIII Description of Device MS3TDV1

Section: 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.

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9150 Microstim MkIII Description of Device Technical
#8028 Microstim MkIII Description of Device
#3295 Microstim MkIII Description of Device MS3TDV1

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Section: 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.

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9150 Microstim MkIII Description of Device Technical
#8028 Microstim MkIII Description of Device
#3295 Microstim MkIII Description of Device MS3TDV1

Section: 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.

Supporting Document IDs
#1017 Microstim EMC rationale

Section: 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.

Supporting Document IDs
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#9407 Microstim MkIII Design Input Device History Y.01 Design History_Microstim DB
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#3353 Microstim MkIII Design Input Device History Manufacturing constraints on the Microstim
#3351 Microstim MkIII Design Input Device History Design Goals MS3DGV1
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

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Notes:
new parts added to new appendix A

Section: 12.7

Protection against mechanical and thermal risks

Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Section: 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.

Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Section: 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.

Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

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Section: 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.

Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

Section: 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.

Supporting Document IDs
#15599 2520000 Microstim DB3 - Patient Lead. (2362 / 1795)

Section: 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.

Supporting Document IDs
#15425 Microstim MkIII Risk analysis reports
#13995 Microstim MkIII Risk analysis reports Yearly Post market survelance
#7592 Microstim MkIII EN ISO 14971:2001 Annex D (FMEA)
#1032 Microstim Risk analysis reports
#1021 Microstim EN ISO 14971:2001 Annex A

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Section: 12.8

Protection against the risks posed to the patient by energy supplies or substances

Section: 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.

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9150 Microstim MkIII Description of Device Technical
#8526 2510000 Microstim DB3 Product Application Details
#3292 Microstim MkIII Description of Device Clinical use
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 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.

Standards Applied
EN 60601-1:2006/A1:2013

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9150 Microstim MkIII Description of Device Technical
#8526 2510000 Microstim DB3 Product Application Details
#3292 Microstim MkIII Description of Device Clinical use
#1059 Microstim Instructions for Use / User Manual Placement Diagram

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Section: 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.

Standards Applied
EN 60601-1:2006/A1:2013

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9150 Microstim MkIII Description of Device Technical
#8526 2510000 Microstim DB3 Product Application Details
#3292 Microstim MkIII Description of Device Clinical use
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13

Information supplied by the manufacturer

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#9150 Microstim MkIII Description of Device Technical
#8526 2510000 Microstim DB3 Product Application Details
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels
#3292 Microstim MkIII Description of Device Clinical use

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Section: 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.

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#9150 Microstim MkIII Description of Device Technical
#8526 2510000 Microstim DB3 Product Application Details
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels
#3295 Microstim MkIII Description of Device MS3TDV1
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 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.

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

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Section: 13.3

The label must bear the following particulars:

Section: 13.3 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;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 13.3 b

the details strictly necessary to identify the device and the contents of the packaging especially for the users;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Microstim MkIII Essential Requirements 23 Sep 2015

Section: 13.3 c

where appropriate, the word ‘STERILE’;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 13.3 d

where appropriate, the batch code, preceded by the word ‘LOT’,or the serial number;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Notes:
user manual and serial number

Section: 13.3 e

where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; (e). This indication may be included in the batch or serial number;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 13.3 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;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 13.3 g

if the device is custom-made, the words ‘custom-made device’;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

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Section: 13.3 h

if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 13.3 i

any special storage and/or handling conditions;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 13.3 j

any special operating instructions;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

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Section: 13.3 k

any warnings and/or precautions to take;

Supporting Document IDs
#12210 Microstim MkIII Instructions for Use / User Manual Danish Certificate of Translation
#12209 Microstim MkIII Instructions for Use / User Manual Danish
#12205 Microstim MkIII Instructions for Use / User Manual English
#5042 Microstim MkIII Instructions for Use / User Manual French
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.3 l

year of manufacture for active devices other than those covered by
(e). This indication may be included in the batch or serial number;

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 13.3 m

where applicable, method of sterilization;

Supporting Document IDs
#9062 Microstim MkIII Sterilisation Microstim Sterilisation

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Section: 13.3 n

in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#8315 Human Blood & derivatives Statement of non use
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 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.

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 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.

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

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Section: 13.6

Where appropriate, the instructions for use must contain the following particulars:

Supporting Document IDs
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels

Section: 13.6 a

the details referred to in Section 13.3, with the exception of (d) and (e);

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 b

the performances referred to in Section 3 and any undesirable side effects;

Section: 13.6 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;

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Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 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;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 e

where appropriate, information to avoid certain risks in connection with implantation of the device;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 f

information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

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Section: 13.6 g

the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 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. 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.
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;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#9062 Microstim MkIII Sterilisation Microstim Sterilisation
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 i

details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);

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Supporting Document IDs
#9062 Microstim MkIII Sterilisation Microstim Sterilisation

Section: 13.6 j

in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

Supporting Document IDs
#8315 Human Blood & derivatives Statement of non use

Section: 13.6

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:

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 k

precautions to be taken in the event of changes in the performance of the device;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 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.;

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Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 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;

Supporting Document IDs
#13136 Medicinal Substances None

Section: 13.6 n

precautions to be taken against any special, unusual risks related to the disposal of the device;

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#9463 Microstim MkIII Labels 250001 Appendix 1 page 20
#9462 Microstim MkIII Labels 250001 box label
#4795 Microstim MkIII Labels
#4794 Microstim MkIII Labels
#4793 Microstim MkIII Labels
#4792 Microstim MkIII Labels
#3301 Microstim MkIII Labels
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 o

medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;

Supporting Document IDs
#13136 Medicinal Substances None

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Section: 13.6 p

degree of accuracy claimed for devices with a measuring function;

Supporting Document IDs
#15573 BS EN 60601-2-10:2015 Nerve Stimulators
#12205 Microstim MkIII Instructions for Use / User Manual English
#8527 2510000 Microstim DB3 Specifications
#1059 Microstim Instructions for Use / User Manual Placement Diagram

Section: 13.6 q

date of issue or the latest revision of the instructions for use.

Supporting Document IDs
#12205 Microstim MkIII Instructions for Use / User Manual English
#1059 Microstim Instructions for Use / User Manual Placement Diagram