

Tom Thumb Essential Requirements 23 Aug 2016

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.

Supporting Document IDs

- #15756 Tom Thumb Residual Risks to Benefits Residual risks 2015
- #15751 Tom Thumb Risk analysis reports Risk assessment
- #14007 Tom Thumb Design Input Device History IMI positive pressure ventilator
- #8489 Tom Thumb EN ISO 14971:2001 Annex D
- #7458 Tom Thumb Design Input Device History valve theory
- #7457 Tom Thumb Design Input Device History Air Oxygen calculations
- #2365 Tom Thumb Design Input Device History Restrictor calculations
- #2364 Tom Thumb Design Input Device History Relief pressures
- #2363 Tom Thumb Design Input Device History Flow calculations
- #2362 Tom Thumb Design Input Device History Device Theory 2005
- #2361 Tom Thumb Design Input Device History Device History & Theory 2004
- #2360 Tom Thumb Design Input Device History Calculations of Flow
- #2183 Tom Thumb EN ISO 14971:2001 Annex A

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),

Standards Applied

- EN ISO 13485:2012
- EN ISO 14971:2012
- EN 60601-1:2006/A1:2013
- EN ISO 9001 2008

Supporting Document IDs

- #15756 Tom Thumb Residual Risks to Benefits Residual risks 2015
- #15751 Tom Thumb Risk analysis reports Risk assessment

Tom Thumb Essential Requirements 23 Aug 2016

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).

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15

#15571 Tom Thumb Instructions for Use User Manual TT480

#15570 Tom Thumb Instructions for Use User Manual 0310027

#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email

#13047 Tom Thumb Instructions for Use User Manual French

#12211 Tom Thumb Instructions for Use User Manual TT495-15

#11732 Tom Thumb Instructions for Use User Manual

Notes:

For use by qualified and trained personnel only

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:

Supporting Document IDs

#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015

#15751 Tom Thumb Risk analysis reports Risk assessment

#2182 Tom Thumb Risk analysis reports Risk analysis 2004

Section: 2 ii

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

Standards Applied

EN ISO 14971:2012

Tom Thumb Essential Requirements 23 Aug 2016

Supporting Document IDs

#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015

#15751 Tom Thumb Risk analysis reports Risk assessment

Section: 2 iii

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

Standards Applied

EN 1041:2008

EN ISO 14971:2012

Supporting Document IDs

#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015

#15751 Tom Thumb Risk analysis reports Risk assessment

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.

Supporting Document IDs

#15751 Tom Thumb Risk analysis reports Risk assessment

#15572 Tom Thumb Instructions for Use / User Manual TT490-15

#15571 Tom Thumb Instructions for Use User Manual TT480

#12211 Tom Thumb Instructions for Use User Manual TT495-15

#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

#8489 Tom Thumb EN ISO 14971:2001 Annex D

#2970 Tom Thumb EN1998 Risk Analysis

#2183 Tom Thumb EN ISO 14971:2001 Annex A

#2182 Tom Thumb Risk analysis reports Risk analysis 2004

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

- #15747 Tom Thumb Post Market Surveillance
- #15587 Tom Thumb Post Market Clinical Follow-up
- #15461 Tom Thumb Packaging Trials and validation
- #15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation
- #14011 Tom Thumb Clinical Trials Reports
- #13680 Tom Thumb Specifications Temperature Range
- #11656 Tom Thumb Literature reviews Use of self-inflating bags
- #9476 Tom Thumb Test Reports Dual Tom Thumb Flowrates
- #7726 Tom Thumb Packaging Trials and validation TT495
- #7724 Tom Thumb Packaging Trials and validation Packagine TT480
- #5120 Tom Thumb Clinical Information / Data
- #3000 Tom Thumb Test Reports Flow checks Test Results
- #2999 Tom Thumb Test Reports TT Peep Results
- #2997 Tom Thumb Validation design compliance
- #2996 Tom Thumb Validation 2005 validation
- #2471 Tom Thumb Test Reports
- #2466 Tom Thumb Clinical Trials Sunderland 1993
- #2462 Tom Thumb Test Reports Wika calibration
- #2460 Tom Thumb Test Reports Flush rayes 2000
- #2247 Tom Thumb Specifications Technical Specification 1997
- #2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004
- #2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004
- #2230 Tom Thumb Clinical Trials RVI 1997
- #2229 Tom Thumb Clinical Trials (R) Clinical Trials 1997

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.

Standards Applied
EN ISO 14971:2012

Tom Thumb Essential Requirements 23 Aug 2016

Supporting Document IDs

#15751 Tom Thumb Risk analysis reports Risk assessment
#15747 Tom Thumb Post Market Surveillance
#15587 Tom Thumb Post Market Clinical Follow-up
#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation
#14011 Tom Thumb Clinical Trials Reports
#11775 Tom Thumb Expected Life of Products
#8489 Tom Thumb EN ISO 14971:2001 Annex D
#5120 Tom Thumb Clinical Information / Data
#2970 Tom Thumb EN1998 Risk Analysis
#2466 Tom Thumb Clinical Trials Sunderland 1993
#2230 Tom Thumb Clinical Trials RVI 1997
#2229 Tom Thumb Clinical Trials (R) Clinical Trials 1997
#2183 Tom Thumb EN ISO 14971:2001 Annex A
#2182 Tom Thumb Risk analysis reports Risk analysis 2004

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

#15461 Tom Thumb Packaging Trials and validation
#7726 Tom Thumb Packaging Trials and validation TT495
#7724 Tom Thumb Packaging Trials and validation Packagine TT480
#2991 Tom Thumb Material Saftey Data Sheet 2004 MH052_MSDS_20050405
#2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004
#2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004

Section: 6

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

Standards Applied

EN ISO 14971:2012

Tom Thumb Essential Requirements 23 Aug 2016

Supporting Document IDs

#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015

#15751 Tom Thumb Risk analysis reports Risk assessment

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

#15587 Tom Thumb Post Market Clinical Follow-up

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'.

Standards Applied

EN ISO 9001 2008

Supporting Document IDs

#7896 Tom Thumb Design Reviews QC24

#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter

#7884 Tom Thumb Specifications of Materials TT component specifications all

#4298 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June

#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206

#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001

#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001

#3008 Tom Thumb Specifications of Materials 1997 Wika

#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001

#3005 Tom Thumb Specifications of Materials 1997 Harlow 001

#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001

#3003 Tom Thumb Specifications of Materials 1997 Buckingham fasteners 001

#2998 Tom Thumb Design Reviews QC24 Drager Design review

#2991 Tom Thumb Material Safety Data Sheet 2004 MH052_MSDS_20050405

#2534 MH052 TDS UK PermaBond

#2456 Tom Thumb Design Reviews QC24 TT Restrictor

#2455 Tom Thumb Design Reviews QC24 Product Review_03

#2454 Tom Thumb Design Reviews QC24 Product Review Restrictor 02

#2453 Tom Thumb Design Reviews QC24 Product Review 02

#2452 Tom Thumb Design Reviews QC24 Product Review 01

#2343 Tom Thumb Specifications of Materials TE gauge 1997 9901-15

#2342 Tom Thumb Specifications of Materials TE Flowmeters

#2341 Tom Thumb Specifications of Materials T E Copper washers
#2340 Tom Thumb Specifications of Materials O rings 1997
#2338 Tom Thumb Specifications of Materials Fomblin grease
#2337 Tom Thumb Specifications of Materials Dial a flow 1994
#2223 Tom Thumb Analysis of complaints Complaints Internal 1994

Section: 7.1 ii

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

Standards Applied
EN ISO 9001 2008

Supporting Document IDs

#7896 Tom Thumb Design Reviews QC24
#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter
#7884 Tom Thumb Specifications of Materials TT component specifications all
#4298 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June
#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206
#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001
#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001
#3008 Tom Thumb Specifications of Materials 1997 Wika
#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001
#3005 Tom Thumb Specifications of Materials 1997 Harlow 001
#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001
#3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001
#2998 Tom Thumb Design Reviews QC24 Drager Design review
#2991 Tom Thumb Material Safety Data Sheet 2004 MH052_MSDS_20050405
#2534 MH052 TDS UK PermaBond
#2456 Tom Thumb Design Reviews QC24 TT Restrictor
#2455 Tom Thumb Design Reviews QC24 Product Review_03
#2454 Tom Thumb Design Reviews QC24 Product Review Restrictor 02
#2453 Tom Thumb Design Reviews QC24 Product Review 02
#2452 Tom Thumb Design Reviews QC24 Product Review 01
#2343 Tom Thumb Specifications of Materials TE gauge 1997 9901-15
#2342 Tom Thumb Specifications of Materials TE Flowmeters
#2341 Tom Thumb Specifications of Materials T E Copper washers
#2340 Tom Thumb Specifications of Materials O rings 1997
#2338 Tom Thumb Specifications of Materials Fomblin grease
#2337 Tom Thumb Specifications of Materials Dial a flow 1994
#2223 Tom Thumb Analysis of complaints Complaints Internal 1994

Tom Thumb Essential Requirements 23 Aug 2016

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,

Standards Applied
EN ISO 9001 2008

Supporting Document IDs

- #15751 Tom Thumb Risk analysis reports Risk assessment
- #15747 Tom Thumb Post Market Surveillance
- #15587 Tom Thumb Post Market Clinical Follow-up
- #15461 Tom Thumb Packaging Trials and validation
- #15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation
- #14011 Tom Thumb Clinical Trials Reports
- #8489 Tom Thumb EN ISO 14971:2001 Annex D
- #7726 Tom Thumb Packaging Trials and validation TT495
- #7724 Tom Thumb Packaging Trials and validation Packagine TT480
- #5120 Tom Thumb Clinical Information / Data
- #2970 Tom Thumb EN1998 Risk Analysis
- #2466 Tom Thumb Clinical Trials Sunderland 1993
- #2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004
- #2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004
- #2230 Tom Thumb Clinical Trials RVI 1997
- #2229 Tom Thumb Clinical Trials (R) Clinical Trials 1997
- #2183 Tom Thumb EN ISO 14971:2001 Annex A
- #2182 Tom Thumb Risk analysis reports Risk analysis 2004

Section: 7.1 iii

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

Standards Applied
EN ISO 9001 2008

Supporting Document IDs

- #7896 Tom Thumb Design Reviews QC24
- #7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter
- #7884 Tom Thumb Specifications of Materials TT component specifications all
- #4298 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June
- #3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206
- #3010 Tom Thumb Specifications of Materials 1998 GSM 4 001
- #3009 Tom Thumb Specifications of Materials 1997 Wika 4 001
- #3008 Tom Thumb Specifications of Materials 1997 Wika
- #3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001
- #3005 Tom Thumb Specifications of Materials 1997 Harlow 001
- #3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001
- #3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001
- #2998 Tom Thumb Design Reviews QC24 Drager Design review

#2991 Tom Thumb Material Safety Data Sheet 2004 MH052_MSDS_20050405
#2534 MH052 TDS UK PermaBond
#2456 Tom Thumb Design Reviews QC24 TT Restrictor
#2455 Tom Thumb Design Reviews QC24 Product Review_03
#2454 Tom Thumb Design Reviews QC24 Product Review Restrictor 02
#2453 Tom Thumb Design Reviews QC24 Product Review 02
#2452 Tom Thumb Design Reviews QC24 Product Review 01
#2343 Tom Thumb Specifications of Materials TE gauge 1997 9901-15
#2342 Tom Thumb Specifications of Materials TE Flowmeters
#2341 Tom Thumb Specifications of Materials T E Copper washers
#2340 Tom Thumb Specifications of Materials O rings 1997
#2338 Tom Thumb Specifications of Materials Fomblin grease
#2337 Tom Thumb Specifications of Materials Dial a flow 1994
#2223 Tom Thumb Analysis of complaints Complaints Internal 1994

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

Standards Applied
EN ISO 9001 2008

Supporting Document IDs

#15751 Tom Thumb Risk analysis reports Risk assessment
#15747 Tom Thumb Post Market Surveillance
#15587 Tom Thumb Post Market Clinical Follow-up
#15461 Tom Thumb Packaging Trials and validation
#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation
#14011 Tom Thumb Clinical Trials Reports
#8489 Tom Thumb EN ISO 14971:2001 Annex D
#7726 Tom Thumb Packaging Trials and validation TT495
#7724 Tom Thumb Packaging Trials and validation Packagene TT480
#5120 Tom Thumb Clinical Information / Data
#2970 Tom Thumb EN1998 Risk Analysis
#2466 Tom Thumb Clinical Trials Sunderland 1993
#2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004
#2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004
#2230 Tom Thumb Clinical Trials RVI 1997
#2229 Tom Thumb Clinical Trials (R) Clinical Trials 1997
#2183 Tom Thumb EN ISO 14971:2001 Annex A
#2182 Tom Thumb Risk analysis reports Risk analysis 2004

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.

Standards Applied

EN 60601-1:2006/A1:2013

Supporting Document IDs

- #15747 Tom Thumb Post Market Surveillance
- #15587 Tom Thumb Post Market Clinical Follow-up
- #15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation
- #14011 Tom Thumb Clinical Trials Reports
- #9476 Tom Thumb Test Reports Dual Tom Thumb Flowrates
- #7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter
- #7884 Tom Thumb Specifications of Materials TT component specifications all
- #5120 Tom Thumb Clinical Information / Data
- #3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206
- #3010 Tom Thumb Specifications of Materials 1998 GSM 4 001
- #3009 Tom Thumb Specifications of Materials 1997 Wika 4 001
- #3008 Tom Thumb Specifications of Materials 1997 Wika
- #3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001
- #3005 Tom Thumb Specifications of Materials 1997 Harlow 001
- #3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001
- #3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001
- #3000 Tom Thumb Test Reports Flow checks Test Results
- #2999 Tom Thumb Test Reports TT Peep Results
- #2991 Tom Thumb Material Safety Data Sheet 2004 MH052_MSDS_20050405
- #2534 MH052 TDS UK PermaBond
- #2471 Tom Thumb Test Reports
- #2466 Tom Thumb Clinical Trials Sunderland 1993
- #2462 Tom Thumb Test Reports Wika calibration
- #2461 Tom Thumb Test Reports Wika cal p02
- #2460 Tom Thumb Test Reports Flush rates 2000
- #2343 Tom Thumb Specifications of Materials TE gauge 1997 9901-15
- #2342 Tom Thumb Specifications of Materials TE Flowmeters
- #2341 Tom Thumb Specifications of Materials T E Copper washers
- #2340 Tom Thumb Specifications of Materials O rings 1997
- #2338 Tom Thumb Specifications of Materials Fomblin grease
- #2337 Tom Thumb Specifications of Materials Dial a flow 1994
- #2230 Tom Thumb Clinical Trials RVI 1997
- #2229 Tom Thumb Clinical Trials (R) Clinical Trials 1997

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 (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.

Supporting Document IDs

#8315 Human Blood & derivatives Statement of non use

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.

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

Supporting Document IDs
#9474 Tom Thumb Leakage and Liquid damage

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.

Standards Applied
EN ISO 14971:2012

Supporting Document IDs
#15751 Tom Thumb Risk analysis reports Risk assessment
#8489 Tom Thumb EN ISO 14971:2001 Annex D
#2970 Tom Thumb EN1998 Risk Analysis
#2183 Tom Thumb EN ISO 14971:2001 Annex A
#2182 Tom Thumb Risk analysis reports Risk analysis 2004

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.

Standards Applied

EN ISO 9001 2008 ISO 13465

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15

#15571 Tom Thumb Instructions for Use User Manual TT480

#12211 Tom Thumb Instructions for Use User Manual TT495-15

#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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

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.

Supporting Document IDs
#2253 Tom Thumb Sterilisation

Section: 8.4

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

Supporting Document IDs
#2253 Tom Thumb Sterilisation

Section: 8.5

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

Supporting Document IDs
#2253 Tom Thumb 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
#15461 Tom Thumb Packaging Trials and validation
#7726 Tom Thumb Packaging Trials and validation TT495
#7724 Tom Thumb Packaging Trials and validation Packagene TT480
#2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004
#2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004

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

#11743 Tom Thumb Labels Part number to Label

#2253 Tom Thumb Sterilisation

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

#15572 Tom Thumb Instructions for Use / User Manual TT490-15

#15571 Tom Thumb Instructions for Use User Manual TT480

#12211 Tom Thumb Instructions for Use User Manual TT495-15

#11747 Tom Thumb Labels Caution Label 0390018 Top Block

#11732 Tom Thumb Instructions for Use User Manual

#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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

Tom Thumb Essential Requirements 23 Aug 2016

Supporting Document IDs

#15751 Tom Thumb Risk analysis reports Risk assessment
#8489 Tom Thumb EN ISO 14971:2001 Annex D
#2970 Tom Thumb EN1998 Risk Analysis
#2183 Tom Thumb EN ISO 14971:2001 Annex A
#2182 Tom Thumb Risk analysis reports Risk analysis 2004
#2176 Tom Thumb EMC rationale

Notes:

new parts added to new appendix A 60601-2- xx are specific standards to specific equipment to be used with 60601 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,

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP
#2970 Tom Thumb EN1998 Risk Analysis
#2183 Tom Thumb EN ISO 14971:2001 Annex A

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,

Supporting Document IDs

#2176 Tom Thumb EMC rationale

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,

Supporting Document IDs

#2176 Tom Thumb EMC rationale

Notes:

I would leave this 9.2

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.

Standards Applied

EN 60601-1:2006/A1:2013

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.

Standards Applied
EN ISO 9001 2008

Supporting Document IDs

#13680 Tom Thumb Specifications Temperature Range
#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001
#3008 Tom Thumb Specifications of Materials 1997 Wika
#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001
#2247 Tom Thumb Specifications Technical Specification 1997

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).

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.

Section: 11.2

Intended radiation

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.

Supporting Document IDs

#9456 Generic CE File Attached to All Ionising Radiation None

Section: 11.4

Instructions

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15

#15571 Tom Thumb Instructions for Use User Manual TT480

#15570 Tom Thumb Instructions for Use User Manual 0310027

#12211 Tom Thumb Instructions for Use User Manual TT495-15

#11732 Tom Thumb Instructions for Use User Manual

#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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.

Supporting Document IDs

#9456 Generic CE File Attached to All Ionising Radiation None

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

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.

Supporting Document IDs
#7440 Tom Thumb Software

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
#7440 Tom Thumb Software

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.

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.

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.

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
#2176 Tom Thumb 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.

Standards Applied
EN ISO 13485:2012
EN ISO 14971:2012
EN 60601-1:2006/A1:2013
EN ISO 9001 2008

Supporting Document IDs
#15751 Tom Thumb Risk analysis reports Risk assessment
#8489 Tom Thumb EN ISO 14971:2001 Annex D
#2970 Tom Thumb EN1998 Risk Analysis
#2183 Tom Thumb EN ISO 14971:2001 Annex A
#2182 Tom Thumb Risk analysis reports Risk analysis 2004

Notes:
new parts added to new appendix A

Section: 12.7

Protection against mechanical and thermal risks

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.

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.

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

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.

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

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.

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

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.

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

Section: 12.8

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

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

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
#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#14046 Tom Thumb Description of Device
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#14046 Tom Thumb Description of Device
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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

#11747 Tom Thumb Labels Caution Label 0390018 Top Block
#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker
#11743 Tom Thumb Labels Part number to Label

Section: 13

Information supplied by the manufacturer

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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.

Standards Applied

EN 980:2008
EN 1041:2008

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#14046 Tom Thumb Description of Device
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11747 Tom Thumb Labels Caution Label 0390018 Top Block
#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker
#11743 Tom Thumb Labels Part number to Label
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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.

Standards Applied
EN 1041:2008

Supporting Document IDs
#11747 Tom Thumb Labels Caution Label 0390018 Top Block
#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker
#11743 Tom Thumb Labels Part number to Label

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;

Standards Applied
EN 1041:2008

Supporting Document IDs
#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge

Section: 13.3 b

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

Standards Applied
EN 1041:2008

Supporting Document IDs
#11742 Tom Thumb Labels TT491 Serial
#11741 Tom Thumb Labels TT490 Serial
#11740 Tom Thumb Labels Serial TT480

Section: 13.3 c

where appropriate, the word 'STERILE';

Section: 13.3 d

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

Supporting Document IDs
#11742 Tom Thumb Labels TT491 Serial
#11741 Tom Thumb Labels TT490 Serial
#11740 Tom Thumb Labels Serial TT480

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;

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;

Section: 13.3 g

if the device is custom-made, the words 'custom-made device';

Section: 13.3 h

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

Section: 13.3 i

any special storage and/or handling conditions;

Section: 13.3 j

any special operating instructions;

Section: 13.3 k

any warnings and/or precautions to take;

Tom Thumb Essential Requirements 23 Aug 2016

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15

#15571 Tom Thumb Instructions for Use User Manual TT480

#15570 Tom Thumb Instructions for Use User Manual 0310027

#12211 Tom Thumb Instructions for Use User Manual TT495-15

#11747 Tom Thumb Labels Caution Label 0390018 Top Block

#11743 Tom Thumb Labels Part number to Label

#11732 Tom Thumb Instructions for Use User Manual

#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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;

Section: 13.3 m

where applicable, method of sterilization;

Supporting Document IDs

#2253 Tom Thumb Sterilisation

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

#8315 Human Blood & derivatives Statement of non use

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

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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.

Section: 13.6

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

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

Section: 13.6 a

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

Standards Applied
EN 1041:2008

Tom Thumb Essential Requirements 23 Aug 2016

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;

Standards Applied
EN 1041:2008

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#15008 Tom Thumb Maintenance Parts required for Annual Service of TT480 and TT490
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP
#2212 Tom Thumb Maintenance Service & Care of Tom Thumb 1994
#2209 Tom Thumb Maintenance

Section: 13.6 e

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

Section: 13.6 f

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

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;

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

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP
#2253 Tom Thumb Sterilisation

Section: 13.6 i

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

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

#9456 Generic CE File Attached to All Ionising Radiation None

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:

Section: 13.6 k

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

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.;

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15

#15571 Tom Thumb Instructions for Use User Manual TT480

#15570 Tom Thumb Instructions for Use User Manual 0310027

#12211 Tom Thumb Instructions for Use User Manual TT495-15

#11732 Tom Thumb Instructions for Use User Manual

#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

#2176 Tom Thumb EMC rationale

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;

Section: 13.6 n

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

Supporting Document IDs

#15572 Tom Thumb Instructions for Use / User Manual TT490-15
#15571 Tom Thumb Instructions for Use User Manual TT480
#15570 Tom Thumb Instructions for Use User Manual 0310027
#12211 Tom Thumb Instructions for Use User Manual TT495-15
#11732 Tom Thumb Instructions for Use User Manual
#8512 Tom Thumb Instructions for Use User Manual NeoPEEP

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
#13135 No Animal Tissues No Animal Substances
#8315 Human Blood & derivatives Statement of non use

Section: 13.6 p

degree of accuracy claimed for devices with a measuring function;

Section: 13.6 q

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

Supporting Document IDs

#15571 Tom Thumb Instructions for Use User Manual TT480

#15570 Tom Thumb Instructions for Use User Manual 0310027

#12211 Tom Thumb Instructions for Use User Manual TT495-15

#11732 Tom Thumb Instructions for Use User Manual

#8512 Tom Thumb Instructions for Use User Manual NeoPEEP