

        **Derek Lamb** 230 Issues **3 Unread** | Imported 25 Aug 12:36:43 | [Out of Office: Future](#)



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Tom Thumb Essencial Requirements Checklist

1 - [Edit Tom Thumb Section 1 Settings](#) Completed by Derek Lamb 02 Sep 2015 Applies

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

Technical Files

Primary Files

[#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

[#14007 Tom Thumb Design Input Device History IMI positive pressure ventilator](#)

[#2360 Tom Thumb Design Input Device History Calculations of Flow](#)

[#2361 Tom Thumb Design Input Device History Device History & Theory 2004](#)

[#2362 Tom Thumb Design Input Device History Device Theory 2005](#)

[#2363 Tom Thumb Design Input Device History Flow calculations](#)

[#2364 Tom Thumb Design Input Device History Relief pressures](#)

[#2365 Tom Thumb Design Input Device History Restrictor calculations](#)

[#7457 Tom Thumb Design Input Device History Air Oxygen calculations](#)

[#7458 Tom Thumb Design Input Device History valve theory](#)

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

Supporting Documents in Section E 4 EN ISO 14971:2007 Annex A

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section Y 2 Design Input Device Design Theory

[#7396 VM3COP16 Design and Design Changes](#)

Supporting Documents in Section Y 14 Design Changes

[#7905 Tom Thumb Design Changes Dual Outlet](#)

[#2451 Tom Thumb Design Changes QC 28](#)

[#2994 Tom Thumb Design Changes 2005 Design Change Rationale](#)

[#2995 Tom Thumb Design Changes 2005 dual outlet taper_G & R](#)

[#7461 Tom Thumb Design Changes 2005](#)

[#7909 Tom Thumb Design Changes 15mm outlets](#)

[#7911 Tom Thumb Design Changes TT480 modification](#)

[#7914 Tom Thumb Drawings 0330296](#)

Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance

[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)

[#2230 Tom Thumb Clinical Trials RVI 1997](#)

[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)

[#5120 Tom Thumb Clinical Information / Data](#)

[#17690 Tom Thumb Post Market Surveillance](#)

[#14011 Tom Thumb Clinical Trials Reports](#)

[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)

[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)

[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1](#)

[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2](#)

[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)

[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)

[#15753 Tom Thumb Clinical Trials Research JSL](#)

[#15754 Tom Thumb Clinical Trials Research](#)

[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)

1 i - [Edit Tom Thumb Section 1 i Settings](#) Completed by Derek Lamb 18 Jul 2017 Does Not Apply

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

Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

[#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015](#)

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section Y 1 Design Input Device History

[#2360 Tom Thumb Design Input Device History Calculations of Flow](#)

[#2361 Tom Thumb Design Input Device History Device History & Theory 2004](#)

[#2362 Tom Thumb Design Input Device History Device Theory 2005](#)

[#2363 Tom Thumb Design Input Device History Flow calculations](#)

[#2364 Tom Thumb Design Input Device History Relief pressures](#)

[#2365 Tom Thumb Design Input Device History Restrictor calculations](#)

[#7457 Tom Thumb Design Input Device History Air Oxygen calculations](#)

[#7458 Tom Thumb Design Input Device History valve theory](#)

[#14007 Tom Thumb Design Input Device History IMI positive pressure ventilator](#)

Supporting Documents in Section Y 2 Design Input Device Design Theory

[#7396 VM3COP16 Design and Design Changes](#)

Supporting Documents in Section Y 14 Design Changes

[#7905 Tom Thumb Design Changes Dual Outlet](#)

[#2451 Tom Thumb Design Changes QC 28](#)

[#2994 Tom Thumb Design Changes 2005 Design Change Rationale](#)

[#2995 Tom Thumb Design Changes 2005 dual outlet taper _G & R](#)

[#7461 Tom Thumb Design Changes 2005](#)

[#7909 Tom Thumb Design Changes 15mm outlets](#)

[#7911 Tom Thumb Design Changes TT480 modification](#)

[#7914 Tom Thumb Drawings 0330296](#)

1 ii - [Edit Tom Thumb Section 1 ii Settings](#) Completed by Derek Lamb 02 Sep 2015 Applies

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).

Standards Applied
Technical Files

Primary Files

[#11732 Tom Thumb Instructions for Use User Manual](#)
[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)
[#13047 Tom Thumb Instructions for Use User Manual French](#)
[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)
[#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](#)
Supporting Documents in Section E 3 Risk analysis reports
[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)
[#21003 Tom Thumb Risk analysis reports Risk assessment](#)
Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A
[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)
[#2970 Tom Thumb EN1998 Risk Analysis](#)
Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D
[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)
Supporting Documents in Section Y 1 Design Input Device History
[#2360 Tom Thumb Design Input Device History Calculations of Flow](#)
[#2361 Tom Thumb Design Input Device History Device History & Theory 2004](#)
[#2362 Tom Thumb Design Input Device History Device Theory 2005](#)
[#2363 Tom Thumb Design Input Device History Flow calculations](#)
[#2364 Tom Thumb Design Input Device History Relief pressures](#)
[#2365 Tom Thumb Design Input Device History Restrictor calculations](#)
[#7457 Tom Thumb Design Input Device History Air Oxygen calculations](#)
[#7458 Tom Thumb Design Input Device History valve theory](#)
[#14007 Tom Thumb Design Input Device History IMI positive pressure ventilator](#)
Supporting Documents in Section Y 14 Design Changes
[#7905 Tom Thumb Design Changes Dual Outlet](#)
[#2451 Tom Thumb Design Changes QC 28](#)
[#2994 Tom Thumb Design Changes 2005 Design Change Rationale](#)
[#2995 Tom Thumb Design Changes 2005 dual outlet taper_G & R](#)
[#7396 VM3COP16 Design and Design Changes](#)

[#7461 Tom Thumb Design Changes 2005](#)

[#7909 Tom Thumb Design Changes 15mm outlets](#)

[#7911 Tom Thumb Design Changes TT480 modification](#)

[#7914 Tom Thumb Drawings 0330296](#)

Supporting Documents in Section L 1 Literature reviews

[#2982 Tom Thumb Literature reviews Neopuff](#)

[#11656 Tom Thumb Literature reviews Use of self-inflating bags](#)

[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)

[#15454 Tom Thumb Literature reviews Aimed leaflet PIP & PEEP against bag](#)

[#15497 Tom Thumb Literature reviews Clinical papers](#)

[#17306 Tom Thumb Literature reviews Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review](#)

[#17307 Tom Thumb Literature reviews T-piece or self inflating bag for positive pressure ventilation during delivery room resuscitation_ An RCT - Resuscitation](#)

[#17330 Tom Thumb Literature reviews Scottish Neonatal Resuscitation Course Manual](#)

[#17331 Tom Thumb Literature reviews Royal Cornwall Newborn guide lines](#)

[#17332 Tom Thumb Literature reviews Nottingham Neonatal Service - Clinical Guidelines](#)

[#17333 Tom Thumb Literature reviews Royal Berkshire GL443 Neonatal Guidelines](#)

[#17334 Resuscitation Guide Neonatal Life support 2005 Tom Thumb Literature reviews Resuscitation Council \(UK\) Newborn Life Support](#)

Supporting Documents in Section E 11 Residual Risks

[#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

Notes:

For use by qualified and trained personnel only

2 i - [Edit Tom Thumb Section 2 i Settings](#) Completed by Derek Lamb 02 Sep 2015 Applies

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

Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

[#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015](#)

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

2 ii - [Edit Tom Thumb Section 2 ii Settings](#) Completed by Derek Lamb 21 Jul 2017 Applies eliminate or reduce risks as far as possible (inherently safe design and construction),

Standards Applied
EN ISO 14971:2012

Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)
[#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015](#)
Supporting Documents in Section E 3 Risk analysis reports
[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)
Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A
[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)
[#2970 Tom Thumb EN1998 Risk Analysis](#)
Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D
[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)
Supporting Documents in Section F 5 Instructions for Use User Manual
[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)
[#5107 Instructions For Use Tom Thumb TT480](#)
[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)
[#8506 Instructions For Use Tom Thumb TT495](#)
[#15571 Tom Thumb Instructions for Use User Manual TT480](#)
[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)
[#11732 Tom Thumb Instructions for Use User Manual](#)
[#13047 Tom Thumb Instructions for Use User Manual French](#)
[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)
[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)
[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)
[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

2 iii - [Edit Tom Thumb Section 2 iii Settings](#) Completed by Derek Lamb 21 Jul 2017 Applies
where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

Standards Applied

Technical Files

Primary Files

[#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

2 iv - [Edit Tom Thumb Section 2 iv Settings](#) Completed by John Lamb 16 Sep 2015 Applies
inform users of the residual risks due to any shortcomings of the protection measures adopted.

Standards Applied

Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)
[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)
[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)
[#2970 Tom Thumb EN1998 Risk Analysis](#)
[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)
[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)
[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)
[#15571 Tom Thumb Instructions for Use User Manual TT480](#)
[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)
Supporting Documents in Section F 5 Instructions for Use User Manual
[#5107 Instructions For Use Tom Thumb TT480](#)
[#8506 Instructions For Use Tom Thumb TT495](#)
[#11732 Tom Thumb Instructions for Use User Manual](#)
[#13047 Tom Thumb Instructions for Use User Manual French](#)
[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)
[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)
[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)
[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

3 - [Edit Tom Thumb Section 3 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#13680 Tom Thumb Specifications Temperature Range](#)
[#2247 Tom Thumb Specifications Technical Specification 1997](#)
[#11656 Tom Thumb Literature reviews Use of self-inflating bags](#)
[#2996 Tom Thumb Validation 2005 validation](#)
[#2007 Tom Thumb Validation design compliance](#)

[#2997 Tom Thumb Validation Design Compliance](#)

[#14011 Tom Thumb Clinical Trials Reports](#)

[#17690 Tom Thumb Post Market Surveillance](#)

[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)

[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)

[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)

[#2230 Tom Thumb Clinical Trials RVI 1997](#)

[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)

[#5120 Tom Thumb Clinical Information / Data](#)

[#2460 Tom Thumb Test Reports Flush rays 2000](#)

[#2462 Tom Thumb Test Reports Wika calibration](#)

[#2471 Tom Thumb Test Reports](#)

[#2999 Tom Thumb Test Reports TT Peep Results](#)

[#3000 Tom Thumb Test Reports Flow checks Test Results](#)

[#9476 Tom Thumb Test Reports Dual Tom Thumb Flowrates](#)

[#15461 Tom Thumb Packaging Trials and validation](#)

[#2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004](#)

[#2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004](#)

[#7724 Tom Thumb Packaging Trials and validation Packagene TT480](#)

[#7726 Tom Thumb Packaging Trials and validation TT495](#)

Supporting Documents in Section Y 15 Validation

[#2458 Tom Thumb Validation Compliance](#)

[#2459 Tom Thumb Validation Project Validation](#)

Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance

[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1](#)

[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2](#)

[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)

[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)

[#15753 Tom Thumb Clinical Trials Research JSL](#)

[#15754 Tom Thumb Clinical Trials Research](#)

[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)

Supporting Documents in Section Y 18 Test and Design Reports

[#2461 Tom Thumb Test Reports Wika cal p02](#)

4 - [Edit Tom Thumb Section 4 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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
Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

[#14011 Tom Thumb Clinical Trials Reports](#)

[#17690 Tom Thumb Post Market Surveillance](#)

[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)

[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)

[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)

[#2230 Tom Thumb Clinical Trials RVI 1997](#)

[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)

[#5120 Tom Thumb Clinical Information / Data](#)

[#11775 Tom Thumb Expected Life of Products](#)

Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance

[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece resuscitator 1](#)

[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece resuscitator 2](#)

[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)

[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)

[#15753 Tom Thumb Clinical Trials Research JSL](#)

[#15754 Tom Thumb Clinical Trials Research](#)

[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)

Supporting Documents in Section G 7 Expected Life of Products

[#20966 Tom Thumb Expected Life of Products Proof1](#)

[#20968 Tom Thumb Expected Life of Products Proof2](#)

Notes:

new parts added to appendix A

5 - [Edit Tom Thumb Section 5 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#15461 Tom Thumb Packaging Trials and validation](#)

[#2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004](#)

[#2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004](#)

[#7724 Tom Thumb Packaging Trials and validation Packagine TT480](#)

[#7726 Tom Thumb Packaging Trials and validation TT495](#)

[#2991 Tom Thumb Material Saftey Data Sheet 2004 MH052_MSDS_20050405](#)

6 - [Edit Tom Thumb Section 6 Settings](#) Completed by Derek Lamb 21 Jul 2017 Applies

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

Standards Applied

Technical Files

Primary Files

[#15756 Tom Thumb Residual Risks to Benefits Residual risks 2015](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance

[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)

[#2230 Tom Thumb Clinical Trials RVI 1997](#)

[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)

[#5120 Tom Thumb Clinical Information / Data](#)

[#17690 Tom Thumb Post Market Surveillance](#)

[#14011 Tom Thumb Clinical Trials Reports](#)

[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)

[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)

[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece resuscitator 1](#)

[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece resuscitator 2](#)

[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)

[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)

[#15753 Tom Thumb Clinical Trials Research JSL](#)

[#15754 Tom Thumb Clinical Trials Research](#)

[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)

6 ii - [Edit Tom Thumb Section 6 ii Settings](#) Completed by Derek Lamb 21 Jul 2017 Applies

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

Standards Applied

Technical Files

Primary Files

[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)

Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance

[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)

[#2230 Tom Thumb Clinical Trials RVI 1997](#)

[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)

[#5120 Tom Thumb Clinical Information / Data](#)

[#17690 Tom Thumb Post Market Surveillance](#)

[#14011 Tom Thumb Clinical Trials Reports](#)

[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)

[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1](#)

[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2](#)

[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)

[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)

[#15753 Tom Thumb Clinical Trials Research JSL](#)

[#15754 Tom Thumb Clinical Trials Research](#)

[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)

7.1 i - [Edit Tom Thumb Section 7.1 i Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206](#)
[#2337 Tom Thumb Specifications of Materials Dial a flow 1994](#)
[#2340 Tom Thumb Specifications of Materials O rings 1997](#)
[#2338 Tom Thumb Specifications of Materials Fomblin grease](#)
[#2341 Tom Thumb Specifications of Materials T E Copper washers](#)
[#2342 Tom Thumb Specifications of Materials TE Flowmeters](#)
[#2343 Tom Thumb Specifications of Materials TE guage 1997 9901-15](#)
[#2534 MH052 TDS UK Permabond](#)
[#3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001](#)
[#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001](#)
[#3005 Tom Thumb Specifications of Materials 1997 Harlow 001](#)
[#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001](#)
[#3008 Tom Thumb Specifications of Materials 1997 Wika](#)
[#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001](#)
[#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001](#)
[#7884 Tom Thumb Specifications of Materials TT component specifications all](#)
[#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter](#)
[#2991 Tom Thumb Material Saftey Data Sheet 2004 MH052 MSDS 20050405](#)
[#2223 Tom Thumb Analysis of complaints Complaints Internal 1994](#)
[#2452 Tom Thumb Design Reviews QC24 Product Review 01](#)
[#2453 Tom Thumb Design Reviews QC24 Product Review 02](#)
[#2454 Tom Thumb Design Reviews QC24 Product Review Restrictor 02](#)
[#2455 Tom Thumb Design Reviews QC24 Product Review 03](#)
[#2456 Tom Thumb Design Reviews QC24 TT Restrictor](#)
[#2998 Tom Thumb Design Reviews QC24 Drager Design review](#)
[#4298 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June](#)
[#7896 Tom Thumb Design Reviews QC24](#)
Supporting Documents in Section T 1 Specifications of Materials
[#7600 Generic CE File Attached to All Specifications of Materials](#)
Supporting Documents in Section Y 16 Design Reviews QC24
[#7441 Tube Holder Design Reviews QC24](#)

7.1 ii - [Edit Tom Thumb Section 7.1 ii Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206](#)
[#2337 Tom Thumb Specifications of Materials Dial a flow 1994](#)
[#2338 Tom Thumb Specifications of Materials Fomblin grease](#)
[#2340 Tom Thumb Specifications of Materials O rings 1997](#)
[#2341 Tom Thumb Specifications of Materials T E Copper washers](#)
[#2342 Tom Thumb Specifications of Materials TE Flowmeters](#)
[#2343 Tom Thumb Specifications of Materials TE guage 1997 9901-15](#)
[#2534 MH052 TDS UK Permabond](#)
[#3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001](#)
[#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001](#)
[#3005 Tom Thumb Specifications of Materials 1997 Harlow 001](#)
[#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001](#)
[#3008 Tom Thumb Specifications of Materials 1997 Wika](#)
[#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001](#)
[#7884 Tom Thumb Specifications of Materials TT component specifications all](#)
[#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter](#)
[#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001](#)
[#2991 Tom Thumb Material Saftey Data Sheet 2004 MH052_MSDS_20050405](#)
[#2223 Tom Thumb Analysis of complaints Complaints Internal 1994](#)
[#2452 Tom Thumb Design Reviews QC24 Product Review 01](#)
[#2453 Tom Thumb Design Reviews QC24 Product Review 02](#)
[#2454 Tom Thumb Design Reviews QC24 Product Review Restrictor 02](#)
[#2455 Tom Thumb Design Reviews QC24 Product Review_03](#)
[#2456 Tom Thumb Design Reviews QC24 TT Restrictor](#)
[#2998 Tom Thumb Design Reviews QC24 Drager Design review](#)
[#4298 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June](#)
[#7896 Tom Thumb Design Reviews QC24](#)
Supporting Documents in Section T 1 Specifications of Materials
[#7600 Generic CE File Attached to All Specifications of Materials](#)
Supporting Documents in Section Y 16 Design Reviews QC24
[#7441 Tube Holder Design Reviews QC24](#)

7.1 ii - [Edit Tom Thumb Section 7.1 ii Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

[#14011 Tom Thumb Clinical Trials Reports](#)

[#17690 Tom Thumb Post Market Surveillance](#)

[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)

[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)

[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)

[#2230 Tom Thumb Clinical Trials RVI 1997](#)

[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)

[#5120 Tom Thumb Clinical Information / Data](#)

[#15461 Tom Thumb Packaging Trials and validation](#)

[#2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004](#)

[#2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004](#)

[#7724 Tom Thumb Packaging Trials and validation Packagine TT480](#)

[#7726 Tom Thumb Packaging Trials and validation TT495](#)

Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance

[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1](#)

[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2](#)

[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)

[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)

[#15753 Tom Thumb Clinical Trials Research JSL](#)

[#15754 Tom Thumb Clinical Trials Research](#)

[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)

7.1 iii - [Edit Tom Thumb Section 7.1 iii Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply
where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.

Standards Applied

Technical Files

Primary Files

[#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206](#)
[#2337 Tom Thumb Specifications of Materials Dial a flow 1994](#)
[#2338 Tom Thumb Specifications of Materials Fomblin grease](#)
[#2340 Tom Thumb Specifications of Materials O rings 1997](#)
[#2341 Tom Thumb Specifications of Materials T E Copper washers](#)
[#2342 Tom Thumb Specifications of Materials TE Flowmeters](#)
[#2343 Tom Thumb Specifications of Materials TE guage 1997 9901-15](#)
[#2534 MH052 TDS UK Permabond](#)
[#3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001](#)
[#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001](#)
[#3005 Tom Thumb Specifications of Materials 1997 Harlow 001](#)
[#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001](#)
[#3008 Tom Thumb Specifications of Materials 1997 Wika](#)
[#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001](#)
[#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001](#)
[#7884 Tom Thumb Specifications of Materials TT component specifications all](#)
[#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter](#)
[#2991 Tom Thumb Material Saftey Data Sheet 2004 MH052 MSDS 20050405](#)
[#2223 Tom Thumb Analysis of complaints Complaints Internal 1994](#)
[#2452 Tom Thumb Design Reviews QC24 Product Review 01](#)
[#2453 Tom Thumb Design Reviews QC24 Product Review 02](#)
[#2454 Tom Thumb Design Reviews QC24 Product Review Restrictor 02](#)
[#2455 Tom Thumb Design Reviews QC24 Product Review 03](#)
[#2456 Tom Thumb Design Reviews QC24 TT Restrictor](#)
[#2998 Tom Thumb Design Reviews QC24 Drager Design review](#)
[#4298 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June](#)
[#7896 Tom Thumb Design Reviews QC24](#)
Supporting Documents in Section T 1 Specifications of Materials
[#7600 Generic CE File Attached to All Specifications of Materials](#)
Supporting Documents in Section Y 16 Design Reviews QC24
[#7441 Tube Holder Design Reviews QC24](#)

7.2 - [Edit Tom Thumb Section 7.2 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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
Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)
[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)
[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)
[#2970 Tom Thumb EN1998 Risk Analysis](#)
[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)
[#14011 Tom Thumb Clinical Trials Reports](#)
[#17690 Tom Thumb Post Market Surveillance](#)
[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)
[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)
[#2230 Tom Thumb Clinical Trials RVI 1997](#)
[#5120 Tom Thumb Clinical Information / Data](#)
[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)
[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)
[#15461 Tom Thumb Packaging Trials and validation](#)
[#2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004](#)
[#2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004](#)
[#7724 Tom Thumb Packaging Trials and validation Packagene TT480](#)
[#7726 Tom Thumb Packaging Trials and validation TT495](#)
Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance
[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece resuscitator 1](#)
[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece resuscitator 2](#)
[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)
[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)
[#15753 Tom Thumb Clinical Trials Research JSL](#)
[#15754 Tom Thumb Clinical Trials Reseach](#)
[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)

7.3 - [Edit Tom Thumb Section 7.3 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206](#)
[#2337 Tom Thumb Specifications of Materials Dial a flow 1994](#)
[#2338 Tom Thumb Specifications of Materials Fomblin grease](#)
[#2340 Tom Thumb Specifications of Materials O rings 1997](#)
[#2341 Tom Thumb Specifications of Materials T E Copper washers](#)
[#2342 Tom Thumb Specifications of Materials TE Flowmeters](#)
[#2343 Tom Thumb Specifications of Materials TE guage 1997 9901-15](#)
[#2534 MH052 TDS UK Permabond](#)
[#3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001](#)
[#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001](#)
[#3005 Tom Thumb Specifications of Materials 1997 Harlow 001](#)
[#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001](#)
[#3008 Tom Thumb Specifications of Materials 1997 Wika](#)
[#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001](#)
[#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001](#)
[#7884 Tom Thumb Specifications of Materials TT component specifications all](#)
[#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter](#)
[#2991 Tom Thumb Material Saftey Data Sheet 2004 MH052_MSDS_20050405](#)
[#14011 Tom Thumb Clinical Trials Reports](#)
[#17690 Tom Thumb Post Market Surveillance](#)
[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)
[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)
[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)
[#2230 Tom Thumb Clinical Trials RVI 1997](#)
[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)
[#5120 Tom Thumb Clinical Information / Data](#)

[#2460 Tom Thumb Test Reports Flush rayes 2000](#)

[#2461 Tom Thumb Test Reports Wika cal p02](#)

[#2462 Tom Thumb Test Reports Wika calibration](#)

[#2471 Tom Thumb Test Reports](#)

[#2999 Tom Thumb Test Reports TT Peep Results](#)

[#3000 Tom Thumb Test Reports Flow checks Test Results](#)

[#9476 Tom Thumb Test Reports Dual Tom Thumb Flowrates](#)

Supporting Documents in Section T 1 Specifications of Materials

[#7600 Generic CE File Attached to All Specifications of Materials](#)

Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance

[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1](#)

[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2](#)

[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)

[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)

[#15753 Tom Thumb Clinical Trials Research JSL](#)

[#15754 Tom Thumb Clinical Trials Research](#)

[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)

7.4 - [Edit Tom Thumb Section 7.4 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#8315 Human Blood & derivatives Statement of non use](#)

Supporting Documents in Section Y 8 Project Diary

[#2369 Tom Thumb Project Diary Project Progress](#)

7.5 - [Edit Tom Thumb Section 7.5 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#9474 Tom Thumb Leakage and Liquid damage](#)

Supporting Documents in Section Z 8 Medicinal Substances

[#13136 Medicinal Substances None](#)

Supporting Documents in Section R 1 Components Breakdown

[#2269 Tom Thumb Components Breakdown](#)
[#2284 Tom Thumb Components Breakdown 4450-12 Blanking nut](#)
[#2285 Tom Thumb Components Breakdown 4701-61 O2 Inlet Christmas tree](#)
[#2287 Tom Thumb Components Breakdown 6575 TE Flowmeters b](#)
[#2288 Tom Thumb Components Breakdown 9901-00 Nut for seating](#)
[#2289 Tom Thumb Components Breakdown 9901-01 Main block](#)
[#15624 Tom Thumb Components Breakdown 9901-02 Flowmeter bolt](#)
[#2291 Tom Thumb Components Breakdown 9901-03 Variable valve housing](#)
[#2292 Tom Thumb Components Breakdown 9901-03-c Safety valve housing](#)
[#2293 Tom Thumb Components Breakdown 9901-04 Main valve adjusting ring](#)
[#2294 Tom Thumb Components Breakdown 9901-04 \(2\) Main valve internal](#)
[#2296 Safety valve seat Tom Thumb Components Breakdown 9901-05-b Safety valve seat](#)
[#2298 Tom Thumb Components Breakdown 9901-06 \(2\) Safety Valve seat](#)
[#2300 Tom Thumb Components Breakdown 9901-08a Main valve housing](#)
[#2302 Tom Thumb Components Breakdown 9901-09 \(2\) Main valve adjusting screw](#)
[#2303 Tom Thumb Components Breakdown 9901-10 Main valve internal stop](#)
[#2304 Tom Thumb Components Breakdown 9901-10a Main valve internal stop](#)
[#2305 Tom Thumb Components Breakdown 9901-10b Main valve internal stop](#)
[#2307 Tom Thumb Components Breakdown 9901-11 \(2\) Main valve internal](#)
[#2310 Tom Thumb Components Breakdown 9901-12 Main valve seat](#)
[#2312 Tom Thumb Components Breakdown 9901-13 Main valve side screw](#)
[#2313 Tom Thumb Components Breakdown 9901-14 Screw](#)
[#2314 Tom Thumb Components Breakdown 9901-15 Wika guage](#)
[#2315 Tom Thumb Components Breakdown 9901-16 O2 Hose 1mtr](#)
[#2316 Tom Thumb Components Breakdown 9901-17](#)
[#2317 Tom Thumb Components Breakdown 9901-18](#)
[#2318 Tom Thumb Components Breakdown 9901-19 Flowmeter bolt with hole](#)
[#2319 Tom Thumb Components Breakdown 9901-20 Rt Angle connector for O2](#)
[#2322 Tom Thumb Components Breakdown 9901-26 Main Valve spring](#)
[#2323 Tom Thumb Components Breakdown 9901-27 Main valve spring](#)
[#2324 Tom Thumb Components Breakdown 9901-28 Copper sealing washer \(diamond\)](#)
[#2325 Tom Thumb Components Breakdown 9901-31 Blanking Bolt](#)
[#2326 Tom Thumb Components Breakdown 9901-34 adapter 15mm male](#)
[#2328 Tom Thumb Components Breakdown 9901-38b Adjustment screw](#)
[#2330 Tom Thumb Components Breakdown 9901-40 precision vavle breakdown](#)
[#2331 Tom Thumb Components Breakdown 99091-06 nut Nut for seating](#)
[#2332 Tom Thumb Components Breakdown 99091-06 nut for seating](#)
[#2333 Tom Thumb Components Breakdown Modura rail screw](#)
[#2334 Tom Thumb Components Breakdown O rings](#)
[#2335 Tom Thumb Components Breakdown Spacer THE2002](#)

[#2336 Tom Thumb Components Breakdown THE 2002 Modurail Clamp](#)
[#7453 Tom Thumb Components Breakdown parts Total photograph](#)
[#15622 Tom Thumb Components Breakdown 9901-01 Main Block original](#)
Supporting Documents in Section T 1 Specifications of Materials
[#2337 Tom Thumb Specifications of Materials Dial a flow 1994](#)
[#2338 Tom Thumb Specifications of Materials Fomblin grease](#)
[#7884 Tom Thumb Specifications of Materials TT component specifications all](#)
[#2340 Tom Thumb Specifications of Materials O rings 1997](#)
[#2341 Tom Thumb Specifications of Materials T E Copper washers](#)
[#2342 Tom Thumb Specifications of Materials TE Flowmeters](#)
[#2343 Tom Thumb Specifications of Materials TE guage 1997 9901-15](#)
[#3003 Tom Thumb Specifications of Materials 1997 Buckingsham fastners 001](#)
[#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001](#)
[#3005 Tom Thumb Specifications of Materials 1997 Harlow 001](#)
[#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001](#)
[#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001](#)
[#3008 Tom Thumb Specifications of Materials 1997 Wika](#)
[#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001](#)
[#2534 MH052 TDS UK Permabond](#)
[#7600 Generic CE File Attached to All Specifications of Materials](#)
[#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206](#)
[#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter](#)
Supporting Documents in Section T 2 Material Saftey Data Sheet
[#2991 Tom Thumb Material Saftey Data Sheet 2004 MH052_MSDS_20050405](#)

7.6 - [Edit Tom Thumb Section 7.6 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)
[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)
[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)
[#2970 Tom Thumb EN1998 Risk Analysis](#)
[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section Y 16 Design Reviews QC24

[#2452 Tom Thumb Design Reviews QC24 Product Review 01](#)

[#2453 Tom Thumb Design Reviews QC24 Product Review 02](#)

[#2454 Tom Thumb Design Reviews QC24 Product Review Restrictor 02](#)

[#2455 Tom Thumb Design Reviews QC24 Product Review_03](#)

[#2456 Tom Thumb Design Reviews QC24 TT Restrictor](#)

[#2998 Tom Thumb Design Reviews QC24 Drager Design review](#)

[#4298 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June](#)

[#7441 Tube Holder Design Reviews QC24](#)

[#2223 Tom Thumb Analysis of complaints Complaints Internal 1994](#)

[#7896 Tom Thumb Design Reviews QC24](#)

Supporting Documents in Section T 1 Specifications of Materials

[#2337 Tom Thumb Specifications of Materials Dial a flow 1994](#)

[#2338 Tom Thumb Specifications of Materials Fomblin grease](#)

[#7884 Tom Thumb Specifications of Materials TT component specifications all](#)

[#2340 Tom Thumb Specifications of Materials O rings 1997](#)

[#2341 Tom Thumb Specifications of Materials T E Copper washers](#)

[#2342 Tom Thumb Specifications of Materials TE Flowmeters](#)

[#2343 Tom Thumb Specifications of Materials TE guage 1997 9901-15](#)

[#3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001](#)

[#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001](#)

[#3005 Tom Thumb Specifications of Materials 1997 Harlow 001](#)

[#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001](#)

[#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001](#)

[#3008 Tom Thumb Specifications of Materials 1997 Wika](#)

[#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001](#)

[#2534 MH052 TDS UK Permabond](#)

[#7600 Generic CE File Attached to All Specifications of Materials](#)

[#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206](#)

[#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter](#)

Notes:

new parts added to appendix A

8.1 - [Edit Tom Thumb Section 8.1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

Supporting Documents in Section T 1 Specifications of Materials

[#2337 Tom Thumb Specifications of Materials Dial a flow 1994](#)

[#2338 Tom Thumb Specifications of Materials Fomblin grease](#)

[#7884 Tom Thumb Specifications of Materials TT component specifications all](#)

[#2340 Tom Thumb Specifications of Materials O rings 1997](#)

[#2341 Tom Thumb Specifications of Materials T E Copper washers](#)

[#2342 Tom Thumb Specifications of Materials TE Flowmeters](#)

[#2343 Tom Thumb Specifications of Materials TE guage 1997 9901-15](#)

[#3003 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001](#)

[#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001](#)

[#3005 Tom Thumb Specifications of Materials 1997 Harlow 001](#)

[#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001](#)

[#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001](#)

[#3008 Tom Thumb Specifications of Materials 1997 Wika](#)

[#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001](#)

[#2534 MH052 TDS UK Permabond](#)

[#7600 Generic CE File Attached to All Specifications of Materials](#)

[#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206](#)

[#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter](#)

8.2 - [Edit Tom Thumb Section 8.2 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#13135 No Animal Tissues No Animal Substances](#)

8.3 - [Edit Tom Thumb Section 8.3 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#2253 Tom Thumb Sterilisation](#)

8.4 - [Edit Tom Thumb Section 8.4 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#2253 Tom Thumb Sterilisation](#)

8.5 - [Edit Tom Thumb Section 8.5 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#2253 Tom Thumb Sterilisation](#)

8.6 - [Edit Tom Thumb Section 8.6 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#15461 Tom Thumb Packaging Trials and validation](#)

[#2244 Tom Thumb Packaging Trials and validation Packaging Trial 2004](#)

[#2245 Tom Thumb Packaging Trials and validation Packaging Photographs 2004](#)

[#7724 Tom Thumb Packaging Trials and validation Packagene TT480](#)

[#7726 Tom Thumb Packaging Trials and validation TT495](#)

8.7 - [Edit Tom Thumb Section 8.7 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.

Standards Applied

Technical Files

Primary Files

[#2253 Tom Thumb Sterilisation](#)

[#11743 Tom Thumb Labels Part number to Label](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

9.1 - [Edit Tom Thumb Section 9.1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

Supporting Documents in Section E 5 Instructions for Use User Manual

Supporting Documents in Section F 3 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

Supporting Documents in Section Y 18 Test and Design Reports

[#2460 Tom Thumb Test Reports Flush rayes 2000](#)

[#2461 Tom Thumb Test Reports Wika cal p02](#)

[#2462 Tom Thumb Test Reports Wika calibration](#)

[#2471 Tom Thumb Test Reports](#)

[#2999 Tom Thumb Test Reports TT Peep Results](#)

[#3000 Tom Thumb Test Reports Flow checks Test Results](#)

[#9476 Tom Thumb Test Reports Dual Tom Thumb Flowrates](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

9.2 - [Edit Tom Thumb Section 9.2 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#2176 Tom Thumb EMC rationale](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section D 5 EMC report

[#12900 Technical Construction File EMC](#)

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

9.2 i - [Edit Tom Thumb Section 9.2 i Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

Notes:

I would leave this as 9.2

9.2 ii - [Edit Tom Thumb Section 9.2 ii Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Notes:

I would leave this 9.2

Primary Files

[#2176 Tom Thumb EMC rationale](#)

Supporting Documents in Section D 5 EMC report

[#12900 Technical Construction File EMC](#)

9.2 iii - [Edit Tom Thumb Section 9.2 iii Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply
the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,

Standards Applied

Technical Files

Notes:

I would leave this 9.2

Primary Files

[#2176 Tom Thumb EMC rationale](#)

9.2 iv - [Edit Tom Thumb Section 9.2 iv Settings](#) Completed by Derek Lamb 21 Jul 2017 Does Not Apply
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.

Standards Applied

Technical Files

Notes:

I would leave this 9.2

Primary Files

9.3 - [Edit Tom Thumb Section 9.3 Settings](#) Completed by Derek Lamb 21 Jul 2017 Applies

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

Technical Files

Primary Files

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Notes:

Manufactured out of Brass No combustible parts

10.1 - [Edit Tom Thumb Section 10.1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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
Technical Files

Primary Files

[#13680 Tom Thumb Specifications Temperature Range](#)
[#2247 Tom Thumb Specifications Technical Specification 1997](#)
[#3008 Tom Thumb Specifications of Materials 1997 Wika](#)
[#3009 Tom Thumb Specifications of Materials 1997 Wika 4 001](#)
[#3007 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001](#)
Supporting Documents in Section Y 1 Design Input Device History
[#2360 Tom Thumb Design Input Device History Calculations of Flow](#)
[#2361 Tom Thumb Design Input Device History Device History & Theory 2004](#)
[#2362 Tom Thumb Design Input Device History Device Theory 2005](#)
[#2363 Tom Thumb Design Input Device History Flow calculations](#)
[#2364 Tom Thumb Design Input Device History Relief pressures](#)
[#2365 Tom Thumb Design Input Device History Restrictor calculations](#)
[#7457 Tom Thumb Design Input Device History Air Oxygen calculations](#)
[#7458 Tom Thumb Design Input Device History valve theory](#)
[#14007 Tom Thumb Design Input Device History IMI positive pressure ventilator](#)
Supporting Documents in Section Y 16 Design Reviews QC24
[#2452 Tom Thumb Design Reviews QC24 Product Review 01](#)
[#2453 Tom Thumb Design Reviews QC24 Product Review 02](#)
[#2454 Tom Thumb Design Reviews QC24 Product Review Restrictor 02](#)
[#2455 Tom Thumb Design Reviews QC24 Product Review_03](#)
[#2456 Tom Thumb Design Reviews QC24 TT Restrictor](#)
[#2998 Tom Thumb Design Reviews QC24 Drager Design review](#)
[#4298 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June](#)
[#7441 Tube Holder Design Reviews QC24](#)
[#2223 Tom Thumb Analysis of complaints Complaints Internal 1994](#)
[#7896 Tom Thumb Design Reviews QC24](#)

Supporting Documents in Section H 3 Clinical Trials Reports Reviews and Post Market Surveillance

[#2229 Tom Thumb Clinical Trials \(R\) Clinical Trials 1997](#)
[#2230 Tom Thumb Clinical Trials RVI 1997](#)
[#2466 Tom Thumb Clinical Trials Sunderland 1993](#)
[#5120 Tom Thumb Clinical Information / Data](#)
[#17690 Tom Thumb Post Market Surveillance](#)
[#14011 Tom Thumb Clinical Trials Reports](#)
[#17411 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up](#)
[#15439 Tom Thumb Risk / benefits assessment and Clinical Re evaluation](#)
[#15731 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1](#)
[#15732 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2](#)
[#15733 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit](#)
[#15734 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P](#)
[#15753 Tom Thumb Clinical Trials Research JSL](#)
[#15754 Tom Thumb Clinical Trials Reseach](#)
[#16043 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits](#)
Supporting Documents in Section Y 18 Test and Design Reports
[#2460 Tom Thumb Test Reports Flush rays 2000](#)
[#2461 Tom Thumb Test Reports Wika cal p02](#)
[#2462 Tom Thumb Test Reports Wika calibration](#)
[#2471 Tom Thumb Test Reports](#)
[#2999 Tom Thumb Test Reports TT Peep Results](#)
[#3000 Tom Thumb Test Reports Flow checks Test Results](#)
[#9476 Tom Thumb Test Reports Dual Tom Thumb Flowrates](#)
Supporting Documents in Section T 1 Specifications of Materials
[#2337 Tom Thumb Specifications of Materials Dial a flow 1994](#)
[#2338 Tom Thumb Specifications of Materials Fomblin grease](#)
[#7884 Tom Thumb Specifications of Materials TT component specifications all](#)
[#2340 Tom Thumb Specifications of Materials O rings 1997](#)
[#2341 Tom Thumb Specifications of Materials T E Copper washers](#)
[#2342 Tom Thumb Specifications of Materials TE Flowmeters](#)
[#2343 Tom Thumb Specifications of Materials TE guage 1997 9901-15](#)
[#3003 Tom Thumb Specifications of Materials 1997 Buckingsham fastners 001](#)
[#3004 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001](#)
[#3005 Tom Thumb Specifications of Materials 1997 Harlow 001](#)
[#3010 Tom Thumb Specifications of Materials 1998 GSM 4 001](#)
[#2534 MH052 TDS UK Permabond](#)
[#7600 Generic CE File Attached to All Specifications of Materials](#)
[#3477 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206](#)

[#7887 Tom Thumb Specifications of Materials Therapy Equipment Flow meter](#)

10.2 - [Edit Tom Thumb Section 10.2 Settings](#) Completed by Derek Lamb 21 Jul 2017 Applies

The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

Standards Applied

Technical Files

Notes:
Clear Display Dial

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

Supporting Documents in Section F 4 Description of Accessories

[#1663 Tom Thumb Description of Accessories Neo-Peep](#)

[#2188 Tom Thumb Description of Accessories Datex-Ohmeda Giraffe Incubator](#)

[#15634 Tom Thumb Description of Accessories](#)

[#2276 Tom Thumb Accessories Photographs DSCF0996](#)

[#2277 Tom Thumb Accessories Photographs DSCF0997](#)

[#2278 Tom Thumb Accessories Photographs DSCF0998](#)

[#2279 Tom Thumb Accessories Photographs DSCF0999](#)

[#2280 Tom Thumb Accessories Photographs DSCF1000](#)

[#2281 Tom Thumb Accessories Photographs DSCF1001](#)

[#15621 Tom Thumb Description of Accessories](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

10.3 - [Edit Tom Thumb Section 10.3 Settings](#)

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).

Primary Files

Supporting Documents in Section F 4 Description of Accessories

[#1663 Tom Thumb Description of Accessories Neo-Peep](#)

[#2188 Tom Thumb Description of Accessories Datex-Ohmeda Giraffe Incubator](#)

[#15634 Tom Thumb Description of Accessories](#)

[#2276 Tom Thumb Accessories Photographs DSCF0996](#)

[#2277 Tom Thumb Accessories Photographs DSCF0997](#)

[#2278 Tom Thumb Accessories Photographs DSCF0998](#)

[#2279 Tom Thumb Accessories Photographs DSCF0999](#)

[#2280 Tom Thumb Accessories Photographs DSCF1000](#)

[#2281 Tom Thumb Accessories Photographs DSCF1001](#)

[#15621 Tom Thumb Description of Accessories](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

11.1 - [Edit Tom Thumb Section 11.1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section Z 12 Ionising Radiation

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.2 - [Edit Tom Thumb Section 11.2 Settings](#)

Intended radiation

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section Z 12 Ionising Radiation

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.2 i - [Edit Tom Thumb Section 11.2 i Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.2 2 - [Edit Tom Thumb Section 11.2 2 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.3 - [Edit Tom Thumb Section 11.3 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

Unintended radiation

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.3 1 - [Edit Tom Thumb Section 11.3 1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.4 - [Edit Tom Thumb Section 11.4 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

Instructions

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

11.4 1 - [Edit Tom Thumb Section 11.4 1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.5 - [Edit Tom Thumb Section 11.5 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

Ionizing radiation

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.5 1 - [Edit Tom Thumb Section 11.5 1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.5 2 - [Edit Tom Thumb Section 11.5 2 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

11.5 3 - [Edit Tom Thumb Section 11.5 3 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

12 - [Edit Tom Thumb Section 12 Settings](#)

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

Standards Applied

Technical Files

Primary Files

12.1 i - [Edit Tom Thumb Section 12.1 i Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#7440 Tom Thumb Software](#)

12.1 ii - [Edit Tom Thumb Section 12.1 ii Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#7440 Tom Thumb Software](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

12.2 - [Edit Tom Thumb Section 12.2 Settings](#)

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.

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 1 Description of Device

[#14046 Tom Thumb Description of Device](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

12.3 - [Edit Tom Thumb Section 12.3 Settings](#) Completed by Derek Lamb 18 Jul 2017 Does Not Apply

Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 1 Description of Device

[#14046 Tom Thumb Description of Device](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

12.4 - [Edit Tom Thumb Section 12.4 Settings](#)

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.

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 1 Description of Device

[#14046 Tom Thumb Description of Device](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

12.5 - [Edit Tom Thumb Section 12.5 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#2176 Tom Thumb EMC rationale](#)

Supporting Documents in Section D 5 EMC report

[#12900 Technical Construction File EMC](#)

12.6 - [Edit Tom Thumb Section 12.6 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

Supporting Documents in Section Y 1 Design Input Device History

[#2360 Tom Thumb Design Input Device History Calculations of Flow](#)

[#2361 Tom Thumb Design Input Device History Device History & Theory 2004](#)

[#2362 Tom Thumb Design Input Device History Device Theory 2005](#)

[#2363 Tom Thumb Design Input Device History Flow calculations](#)

[#2364 Tom Thumb Design Input Device History Relief pressures](#)

[#2365 Tom Thumb Design Input Device History Restrictor calculations](#)

[#7457 Tom Thumb Design Input Device History Air Oxygen calculations](#)

[#7458 Tom Thumb Design Input Device History valve theory](#)

[#14007 Tom Thumb Design Input Device History IMI positive pressure ventilator](#)

Supporting Documents in Section Y 2 Design Input Device Design Theory

[#7396 VM3COP16 Design and Design Changes](#)

Notes:

new parts added to new appendix A

12.7 - [Edit Tom Thumb Section 12.7 Settings](#)

Protection against mechanical and thermal risks

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

12.7 1 - [Edit Tom Thumb Section 12.7 1 Settings](#)

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.

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

12.7 2 - [Edit Tom Thumb Section 12.7 2 Settings](#)

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

Technical Files

Primary Files

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

12.7 3 - [Edit Tom Thumb Section 12.7 3 Settings](#)

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

Technical Files

Primary Files

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

12.7 4 - [Edit Tom Thumb Section 12.7 4 Settings](#)

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

Technical Files

Primary Files

12.7 5 - [Edit Tom Thumb Section 12.7 5 Settings](#)

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

Technical Files

Primary Files

Supporting Documents in Section E 3 Risk analysis reports

[#2182 Tom Thumb Risk analysis reports Risk analysis 2004](#)

[#21003 Tom Thumb Risk analysis reports Risk assessment](#)

Supporting Documents in Section E 4 EN ISO 14971:2001 Annex A

[#2183 Tom Thumb EN ISO 14971:2001 Annex A](#)

[#2970 Tom Thumb EN1998 Risk Analysis](#)

Supporting Documents in Section E 5 EN ISO 14971:2001 Annex D

[#8489 Tom Thumb EN ISO 14971:2001 Annex D](#)

12.8 - [Edit Tom Thumb Section 12.8 Settings](#)

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

Standards Applied

Technical Files

Primary Files

12.8 1 - [Edit Tom Thumb Section 12.8 1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#14046 Tom Thumb Description of Device](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

12.8 2 - [Edit Tom Thumb Section 12.8 2 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#14046 Tom Thumb Description of Device](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

12.9 - [Edit Tom Thumb Section 12.9 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#11743 Tom Thumb Labels Part number to Label](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

Supporting Documents in Section F 1 Description of Device

[#14046 Tom Thumb Description of Device](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13 - [Edit Tom Thumb Section 13 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

Information supplied by the manufacturer

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

13.1 - [Edit Tom Thumb Section 13.1 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#14046 Tom Thumb Description of Device](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.2 - [Edit Tom Thumb Section 13.2 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#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](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 - [Edit Tom Thumb Section 13.3 Settings](#)

The label must bear the following particulars:

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 a - [Edit Tom Thumb Section 13.3 a Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

Supporting Documents in Section F 7 Labels

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 b - [Edit Tom Thumb Section 13.3 b Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply
the details strictly necessary to identify the device and the contents of the packaging especially for the users;

Standards Applied

Technical Files

Primary Files

[#11740 Tom Thumb Labels Serial TT480](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 c - [Edit Tom Thumb Section 13.3 c Settings](#)

where appropriate, the word 'STERILE';

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 d - [Edit Tom Thumb Section 13.3 d Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply where appropriate, the batch code, preceded by the word 'LOT', or the serial number;

Standards Applied

Technical Files

Notes:

user manual and serial number

Primary Files

[#11740 Tom Thumb Labels Serial TT480](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 e - [Edit Tom Thumb Section 13.3 e Settings](#)

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;

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 f - [Edit Tom Thumb Section 13.3 f Settings](#)

where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 g - [Edit Tom Thumb Section 13.3 g Settings](#)

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

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 h - [Edit Tom Thumb Section 13.3 h Settings](#)

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

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 i - [Edit Tom Thumb Section 13.3 i Settings](#)

any special storage and/or handling conditions;

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 j - [Edit Tom Thumb Section 13.3 j Settings](#)

any special operating instructions;

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

13.3 k - [Edit Tom Thumb Section 13.3 k Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply
any warnings and/or precautions to take;

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 I - [Edit Tom Thumb Section 13.3 I Settings](#)

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

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.3 m - [Edit Tom Thumb Section 13.3 m Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

where applicable, method of sterilization;

Standards Applied

Technical Files

Primary Files

[#2253 Tom Thumb Sterilisation](#)

13.3 n - [Edit Tom Thumb Section 13.3 n Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#8315 Human Blood & derivatives Statement of non use](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.4 - [Edit Tom Thumb Section 13.4 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

13.5 - [Edit Tom Thumb Section 13.5 Settings](#)

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.

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.6 - [Edit Tom Thumb Section 13.6 Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

13.6 a - [Edit Tom Thumb Section 13.6 a Settings](#)

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

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

13.6 b - [Edit Tom Thumb Section 13.6 b Settings](#)

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

Standards Applied

Technical Files

Primary Files

13.6 c - [Edit Tom Thumb Section 13.6 c Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

13.6 d - [Edit Tom Thumb Section 13.6 d Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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;

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#15008 Tom Thumb Maintenance Parts required for Annual Service of TT480 and TT490](#)

[#2209 Tom Thumb Maintenance](#)

[#2212 Tom Thumb Maintenance Service & Care of Tom Thumb 1994](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

Supporting Documents in Section G 1 Maintenance

[#2210 Tom Thumb Maintenance medical-devices.gov](#)

[#2211 Tom Thumb Maintenance Oxygen Hose Maintenance](#)

13.6 e - [Edit Tom Thumb Section 13.6 e Settings](#)

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

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

13.6 f - [Edit Tom Thumb Section 13.6 f Settings](#)

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

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

13.6 g - [Edit Tom Thumb Section 13.6 g Settings](#)

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

Primary Files

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

13.6 h - [Edit Tom Thumb Section 13.6 h Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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;

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#2253 Tom Thumb Sterilisation](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.6 i - [Edit Tom Thumb Section 13.6 i Settings](#)

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

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section O 1 Sterilisation

[#2253 Tom Thumb Sterilisation](#)

13.6 j - [Edit Tom Thumb Section 13.6 j Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply
in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

Standards Applied

Technical Files

Primary Files

[#9456 Generic CE File Attached to All Ionising Radiation None](#)

Supporting Documents in Section Z 11 Carcinogenic Substances

[#9455 Carcinogenic Substances](#)

13.6 - [Edit Tom Thumb Section 13.6 Settings](#)

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:

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.6 k - [Edit Tom Thumb Section 13.6 k Settings](#)

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

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

13.6 I - [Edit Tom Thumb Section 13.6 I Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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.;

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#2176 Tom Thumb EMC rationale](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

13.6 m - [Edit Tom Thumb Section 13.6 m Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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;

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section Y 8 Project Diary

[#2369 Tom Thumb Project Diary Project Progress](#)

13.6 n - [Edit Tom Thumb Section 13.6 n Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

Supporting Documents in Section F 7 Labels

[#11748 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge](#)

[#11744 Tom Thumb Labels 0390010 Adjustable Value Sticker](#)

[#11743 Tom Thumb Labels Part number to Label](#)

[#5922 Tom Thumb Labels mediprema labels](#)

[#2204 Tom Thumb Labels Tomb Thumb Infant Resuscitator](#)

[#11746 Tom Thumb Labels 0390017 Front of Gauge Sticker](#)

[#11741 Tom Thumb Labels TT490 Serial](#)

[#11747 Tom Thumb Labels Caution Label 0390018 Top Block](#)

[#15638 Tom Thumb Labels Original labels](#)

[#11740 Tom Thumb Labels Serial TT480](#)

[#11742 Tom Thumb Labels TT491 Serial](#)

[#11745 Tom Thumb Labels 0390015 Front Block Logo Sticker](#)

[#2254 Tom Thumb Parts List Adj label 04](#)

[#20970 Tom Thumb Labels Top Box Sticker example](#)

13.6 o - [Edit Tom Thumb Section 13.6 o Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#13135 No Animal Tissues No Animal Substances](#)

[#8315 Human Blood & derivatives Statement of non use](#)

[#13136 Medicinal Substances None](#)

Supporting Documents in Section Y 8 Project Diary

[#2369 Tom Thumb Project Diary Project Progress](#)

13.6 p - [Edit Tom Thumb Section 13.6 p Settings](#)

degree of accuracy claimed for devices with a measuring function;

Standards Applied

Technical Files

Primary Files

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

Supporting Documents in Section M 3 Specifications

[#2247 Tom Thumb Specifications Technical Specification 1997](#)

[#13680 Tom Thumb Specifications Temperature Range](#)

13.6 q - [Edit Tom Thumb Section 13.6 q Settings](#) Completed by John Lamb 16 Sep 2015 Does Not Apply

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

Standards Applied

Technical Files

Primary Files

[#8512 Tom Thumb Instructions for Use User Manual NeoPEEP](#)

[#11732 Tom Thumb Instructions for Use User Manual](#)

[#12211 Tom Thumb Instructions for Use User Manual TT495-15](#)

[#15570 Tom Thumb Instructions for Use User Manual 0310027](#)

[#15571 Tom Thumb Instructions for Use User Manual TT480](#)

Supporting Documents in Section F 5 Instructions for Use User Manual

[#15572 Tom Thumb Instructions for Use / User Manual TT490-15](#)

[#5107 Instructions For Use Tom Thumb TT480](#)

[#8506 Instructions For Use Tom Thumb TT495](#)

[#13047 Tom Thumb Instructions for Use User Manual French](#)

[#15509 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email](#)

[#15510 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality](#)

[#15511 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch High Quality 5mm bleed](#)