# ARCHIVE DOCUMENTS

| Section. | Description. | Document. | Archived |
|---|---|---|---|
| i | Preliminary Outline | Introduction<br>Amendment control | Yes<br>Yes |
| A | Index of documentation.<br>Location of documents | Index of documentation.<br>Location of documents. | Yes<br>Yes |
| B | EC Declaration of conformance | Certificate(s) | Yes |
| | Notified body certification | Certificate(s) | Yes |
| | Certification BS EN ISO 9001:2000 | Certificate(s) | Yes |
| C | Essential requirements | Essential requirements | Yes |
| | EN standards | EN Standards | Yes |
| D | Classification rationale<br>Flow chart | Classification rationale<br>Device Classification rules | Yes |
| | EMC rationale | EMC rationale | Yes |
| | EMC report | EMC report | Yes |
| E | Risk analysis Class IIb Tom Thumb | Certificate(s) | Yes |
| | Reports | Risk Management Defnitions<br>Risk Analysis Report | Yes |
| | EN ISO 14971:2001 Annex A | EN ISO 14971:2001 Annex A | Yes |
| | EN ISO 14971:2001 Annex D | EN ISO 14971:2001 Annex D | Yes |
| F | Description device | Description of Device | Yes |
| | | Viamed Tom Thumb leaflet | Yes |
| | Accessories | Description of accessories | Yes |
| | Instructions | User manual | Yes |
| | Labels | Labels | Yes |
| | Information | Training Document | Yes |
| G | Maintenance | Service Manual<br>Service Procedures – VM3COP50.11 - 50.16 | Yes<br>No |
| | Product life | Product life | Yes |
| | Product changes | Product changes | Yes |
| HI | Analysis of complaints/user feedback | Customer complaints<br>User Feedback<br>Product Reviews<br>Medical Device Alerts | Yes |
| JK | Location of responsibilities | Location of responsibilities | Yes |
| | Manufacturing route | Manufacturing route | Yes |
| | Work instructions and tests | W.I. & Test Method<br>Tooling List<br>VM3COP50.01 - 50.06 | Yes<br>Yes<br>No |
| | Sub assemblies & circuit diagrams | Electro-Technical Drawings | Yes |
| L | Literature reviews | Fisher & Paykel Neo-puff<br>Hill-Rom Resuscitaire | Yes |
| M | Packaging trials and validation | Packaging Info<br>Pictorial Info | Yes |
| N | Quality Plan | Quality plan<br>QA Procedures QC33 a-d<br>Test Instructions<br>QA Agreements | Yes<br>No<br>No<br>Yes |
| | Sterilisation | Sterilisation | Yes |
| O | Design File | Contents<br>Design Documentation | |
| PQ | Not Used | --------- | |
| R | Components Breakdown | Complete Parts List | Yes |
| S | Photographs | Original Tom Thumb & accessories | Yes |
| T | Specifications of Materials | Accessories<br>Components | Yes<br>Yes |
| UV | Purchase specifications | All Suppliers | Yes |

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|---|---|---|---|
| WX | Not Used | --------- | |
| YZ | Archives | List of Archived Documents | No |

| Section. | Description. | Document. | Archived |
|---|---|---|---|
| O(01) | Device History & Theory | Device History & Theory<br>Design history | |
| O(02) | Specification Brief | P03 – Specification Brief<br>Device Specification, QC22 | |
| O(03) | Confidentiality Agreements | | |
| O(04) | Not Used | | |
| O(05) | Time Scale | QC25 | |
| O(06) | | | |
| O(07) | Project Progress | Project Diary<br>QC25 | |
| O(08) | Work logs | | |
| O(09) | Expenditure | | |
| O(10) | Not Used | | |
| O(11) | Clinical evaluation | Clinical evaluation | |
| O(12) | Preliminary drawings | | |
| O(13) | Risk assessment | | |
| O(14) | Final Drawings | | |
| | Working Drawings | | |
| O(16) | Design Changes | | |
| O(17) | Validation | Project Validation | |
| O(18) | Quotations | | |
| O(19) | Source codes | | |
| O(20) | Design reviews | | |
| O(21) | Purchases | | |
| O(22) | Test reports | | |
| O(23) | | | |
| O(24) | Final inspection & test | | |
| O(25) | Type examinations | IEC 601 | |
| O(26) | EMC tests & results | | |
| O(27) | Clinical Trial Reports | | |
| O(28) | Biocompatiblity | | |
| O(28) | Compatibility Trials | | |
| O(30) | Final costings | | |
| O(31) | Not Used | | |
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## Index of Documentation.

| Section. | Description. | Ref MDD / Ref ISO 9001. | Document. | Status. | A/NA. | Done. |
|---|---|---|---|---|---|---|
| i | Preliminary Outline | | Introduction<br>Amendment control | | A<br>A | √<br>√ |
| A | Index of documentation.<br>Location of documents | | Index of documentation.<br>Location of documents. | | A<br>A | √<br>√ |
| B | EC Declaration of conformance | Ann II, V, VI | Certificate(s) | | A | √ |
| | Notified body certification | | Certificate(s) | | A | √ |
| | Certification BS EN ISO 9001:2000 | | Certificate(s) | | A | √ |
| | Certification ISO 13485:2003 | | Certificate(s) | | A | √ |
| | Product Trade Mark | | Certificate | | A | √ |
| C | Essential requirements | Art 3 | Essential requirements | | A | √ |
| | EN standards | Ann II para 3.2c | EN Standards | | A | √ |
| D | Classification rationale & Decision Path | Ann IX | Classification rationale<br>Device Classification<br>Device Classification rules | | A<br>A<br>A | √<br>√<br>√ |
| | EMC rationale | | EMC rationale | | N/A | √ |
| | EMC report | | EMC report | | N/A | -- |
| E | Risk analysis Class IIb Tom Thumb | Ann II para 3.2c | Certificate(s) | | A | √ |
| | Reports | | Risk Management Definitions<br>Risk Analysis Report | | A<br>A | √<br>√ |
| | EN ISO 14971:2001 Annex A | | EN ISO 14971:2001 Annex A | | A | √ |
| | EN ISO 14971:2001 Annex D | | EN ISO 14971:2001 Annex D | | A | √ |
| F | Description device | Ann II para 3.1 | Description of Device | | A | √ |
| | | | Viamed Tom Thumb leaflet | | A | √ |
| | Accessories | Ann II para 3.1 | Description of accessories | | A | √ |
| | Instructions | Ann I para 13 | User manual | | A | √ |
| | Labels | Ann I para 13 | Labels | | A | √ |
| | Information | | Training Document | | A | √ |
| G | Maintenance | | Service Manuals<br>Service Manual – Valves<br>Assembly Drawings<br>Service Procedures | | A<br>A<br>A<br>A | √<br>√<br>√<br>√ |
| | Product life | Para 4.5 | Product life | | A | √ |
| | Product changes | Ann II,V,VI para 3.4 | Product changes | | A | √ |
| HI | Analysis of complaints/user feedback | Ann II, V, VI para 3.1<br>Art 15, Annexe X | Customer complaints, user feedback & Clinical Trials<br>Product Reviews<br>Medical Device Alerts | | A<br>A<br>A<br>A | √<br>√<br>√<br>√ |
| JK | Location of responsibilities | Ann II para 3.1 | Location of responsibilities | | A | √ |
| | Manufacturing route | | Manufacturing route | | A | √ |
| | Work instructions and tests | | W.I. & Test Method<br>Tooling List | | A<br>A | √<br>√ |
| | Sub assemblies & circuit diagrams | | Electro-Technical Drawings | | N/A | -- |
| L | Literature reviews | | Fisher & Paykel Neo-puff | | A | √ |
| M | Packaging trials and validation | | Packaging Info<br>Pictorial Info | | A<br>A | √ |
| N | Quality Plan | | Quality plan<br>Test Instructions<br>QA Agreements | | A<br>A<br>A | √<br>√<br>√ |
| O | Sterilisation | | Sterilisation | | A | √ |
| PQ | Not Used | | --- | | N/A | -- |

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|---|---|---|---|---|---|---|
| R | Components Breakdown | | Complete Parts List<br>Pictorial Info | | A<br>A | √<br>√ |
| S | Photographs | | Original Tom Thumb & accessories | | A | √ |
| T | Specifications of Materials | | Accessories, Block, Clamping, Connectors, Flowmeters, Valves, Labels | | A | √ |
| UV | Purchase specifications | | Supplier Details<br>Therapy Equipment, G & R Hydroparts, Newsham Engineering, WIKA, MAJ | | A<br>A | √<br>√ |
| WX | Archives | | List of Archived Documents | | A | √ |
| YZ | Design File | | Contents<br>Design Documentation | | A<br>A | √<br>√ |

| Section. | Description. | Ref MDD / Ref ISO 9001. | Document. | Status. | A/NA. | Done. |
|---|---|---|---|---|---|---|
| YZ | Design File | | Section Y – Design Input<br>Section Z – Design Output | | A<br>A | √<br>√ |
| Y(01) | History & Theory | | Introduction –<br>Device History & Theory<br>Design history | | <br>A<br>A | <br>√<br>√ |
| Y(02) | Specification | | Device Specification, QC22<br>Specification Brief | | A<br>A | √<br>√ |
| Y(03) | Confidentiality Agreements | | By Company Name | | A | |
| Y(04) | Design Calculations | | Calculations<br>Flow Rates | | A<br>A | √<br>√ |
| Y(05) | Time Scale | | QC23 | | A | √ |
| Y(06) | Design Compliance | | Compliance Matrix | | A | √ |
| Y(07) | Project Progress | | Project Diary<br>Design and Development<br>QC25 Progress Report | | N/A<br>A<br>A | --<br>√<br>√ |
| Y(08) | Work logs | | QC 26 | | A | √ |
| Y(09) | Expenditure | | QC 27 Purchases | | A | √ |
| Y(10) | Preliminary drawings | | Sketches<br>Drawings | | A<br>A | √<br>√ |
| Y(11) | Final Drawings | | Final drawing input | | A | √ |
| | Working Drawings | | Final Viamed Drawings | | A | √ |
| Y(12) | Design Changes | | QC 28 | | A | √ |
| Y(13) | Source codes | | Source codes | | N/A | -- |
| Z(14) | Validation | | Project Validation QC30 | | A | √ |
| Z(15) | Design reviews | | QC 24 | | A | √ |
| Z(16) | Purchases | | Copy Purchase Orders | | A | √ |
| Z(17) | Test reports | Ann II para 3.2 | Various reports | | A | √ |
| Z(18) | Final inspection & test | | Internal Test results | | A | √ |
| Z(19) | Type examinations | Ann V, VI | IEC 601 | | A | √ |
| Z(20) | EMC tests & results | | Statement | | A | √ |
| Z(21) | Bio-compatibility | Ann II para 3.2c | Statement | | A | √ |
| Z(22) | Compatibility Trials | | Statement | | A | √ |
| Z(23) | Documentation | | Checklist QC29 | | A | √ |
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