# 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 |

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|---|---|---|---|
| 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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