

File ID15 Envitec Oxygen Sensors Essential Requirements 10 Nov 2017

| General Requirement  | Applied Standards | Notes         | Files                                             |
|----------------------|-------------------|---------------|---------------------------------------------------|
| ER Section Reference | Applied Standards | Section Notes | #DOCID *FolderLocation(s)<br>Document Description |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------|-------------------|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1                   | EN ISO 14971:2012 |       | <p>#16320 *M 3 *BSI 3<br/>0110021 Specification Datasheet</p> <p>#12322 *BSI 3 *M 3<br/>0110023 Specification Datasheet</p> <p>#12328 *BSI 3 *M 3<br/>0110040 Specification Datasheet</p> <p>#12324 *M 3 *BSI 3<br/>0110044 Specification Datasheet</p> <p>#15142 *M 3 *BSI 3<br/>0110045 Oxygen Sensors Specifications R-45V datasheet</p> <p>#12326 *M 3 *BSI 3<br/>0110047 Specification Datasheet</p> <p>#22375<br/>CHART 35 Products On Market Risk Management Plan Post Market Surveillance</p> <p>#22371<br/>Chart 36 Risk Management Existing Products</p> <p>#20910 *BSI 10 *H 3 *BSI 13 *BSI 12<br/>Envitec Oxygen Sensors Clinical Trials Reports Reviews and Post Market Surveillance Clinical Evaluation</p> <p>#16167 *Y 14<br/>Envitec Oxygen Sensors Design Changes design change of the inner cell</p> <p>#22868 *Y 1<br/>Envitec Oxygen Sensors Design Input Device History Oxygen sensors Linearity &amp; Cross interference</p> <p>#21154 *Y 1 *BSI 8<br/>Envitec Oxygen Sensors Design Input Device History Design Input specifications</p> <p>#20115 *H 3 *BSI 13 *BSI 10<br/>Envitec Oxygen Sensors Post Market Surveillance</p> <p>#21619 *Z 2 *Y 15<br/>Envitec Oxygen Sensors QA Test Results Envitec Oxygen Sensors Validation Batch filed from gmail 2015-10-20</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------------------|-------------------|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                   |       | <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#21540 *M 3<br/>Envitec Oxygen Sensors Specifications 001-05-<br/>Specification_Vandagraph_Ltd_OOI101-1-0</p> <p>#14367 *M 3<br/>Envitec Oxygen Sensors Specifications 0110021 Specification Datasheet v1.0</p> <p>#14365 *M 3 *BSI 3<br/>Envitec Oxygen Sensors Specifications 0110042 Specification Datasheet v1.1</p> <p>#21542 *M 3<br/>Envitec Oxygen Sensors Specifications 0110217 labelling artwork approval</p> <p>#21864 *M 3<br/>Envitec Oxygen Sensors Specifications 0110217 R-17VAN Specification datasheet<br/>v1.0 2017-08-24_06_09_17</p> <p>#15143 *M 3<br/>Envitec Oxygen Sensors Specifications Envitec OOM-106 datasheet</p> <p>#21613 *Y 15<br/>Envitec Oxygen Sensors Validation</p> <p>#21617 *Z 2 *Y 15<br/>Envitec Oxygen Sensors Validation Batch filed from gmail 2015-08-11</p> <p>#21615 *Z 2 *Y 15<br/>Envitec Oxygen Sensors Validation Batch filed from gmail 2015_2017</p> <p>#22872 *Y 15<br/>Envitec Oxygen Sensors Validation Oxygen sensors Linearity &amp; Cross Interference</p> <p>#22173<br/>Generic CE File Attached to All Risk management plan</p> <p>#16107 *Y 14<br/>Oxygen sensor R-30V Design Changes 0110040 New Inner Cell</p> <p>#14359 *M 3 *BSI 3</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------|-------------------|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                   |       | <p>Oxygen Sensors Specifications 0110071 Specification Datasheet v1.0</p> <p>#17618 *M 3 *BSI 3<br/>Specification Datasheet - 0110043</p> <p>#17620 *M 3 *BSI 3<br/>Specification Datasheet - 0110048</p> <p>#17622 *M 3 *BSI 3<br/>Specification Datasheet - 0110049</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> <p>#7396<br/>VM3COP16 Design and Design Changes</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------|-------------------|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 i                 |                   |       | <p>#22375<br/>CHART 35 Products On Market Risk Management Plan Post Market Surveillance</p> <p>#16167 *Y 14<br/>Envitec Oxygen Sensors Design Changes design change of the inner cell</p> <p>#22868 *Y 1<br/>Envitec Oxygen Sensors Design Input Device History Oxygen sensors Linearity &amp; Cross interference</p> <p>#21154 *Y 1 *BSI 8<br/>Envitec Oxygen Sensors Design Input Device History Design Input specifications</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#16107 *Y 14<br/>Oxygen sensor R-30V Design Changes 0110040 New Inner Cell</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed's Envitec Oxygen Sensors Risk Assesment</p> <p>#7396<br/>VM3COP16 Design and Design Changes</p> |

| General Requirement | Applied Standards | Notes              | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------|-------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 ii                |                   | Internal Component | <p>#22375<br/>CHART 35 Products On Market Risk Management Plan Post Market Surveillance</p> <p>#16167 *Y 14<br/>Envitec Oxygen Sensors Design Changes design change of the inner cell</p> <p>#22868 *Y 1<br/>Envitec Oxygen Sensors Design Input Device History Oxygen sensors Linearity &amp; Cross interference</p> <p>#21154 *Y 1 *BSI 8<br/>Envitec Oxygen Sensors Design Input Device History Design Input specifications</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#16107 *Y 14<br/>Oxygen sensor R-30V Design Changes 0110040 New Inner Cell</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed's Envitec Oxygen Sensors Risk Assesment</p> <p>#7396<br/>VM3COP16 Design and Design Changes</p> |

| General Requirement | Applied Standards | Notes                                       | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------------|-------------------|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2 i                 |                   | Design Drawings,label, Instructions For Use | <p>#16320 *M 3 *BSI 3<br/>0110021 Specification Datasheet</p> <p>#12322 *BSI 3 *M 3<br/>0110023 Specification Datasheet</p> <p>#12328 *BSI 3 *M 3<br/>0110040 Specification Datasheet</p> <p>#12330 *BSI 3<br/>0110041 Specification Datasheet</p> <p>#12324 *M 3 *BSI 3<br/>0110044 Specification Datasheet</p> <p>#15142 *M 3 *BSI 3<br/>0110045 Oxygen Sensors Specifications R-45V datasheet</p> <p>#12326 *M 3 *BSI 3<br/>0110047 Specification Datasheet</p> <p>#22375<br/>CHART 35 Products On Market Risk Management Plan Post Market Surveillance</p> <p>#22371<br/>Chart 36 Risk Management Existing Products</p> <p>#16701 *N 1 *BSI 0 *BSI 3<br/>Envitec Oxygen Sensor Quality Assurance agreement Appendix 1</p> <p>#20910 *BSI 10 *H 3 *BSI 13 *BSI 12<br/>Envitec Oxygen Sensors Clinical Trials Reports Reviews and Post Market Surveillance Clinical Evaluation</p> <p>#17615 *F 4 *BSI 4<br/>Envitec Oxygen Sensors Description of Accessories</p> <p>#22868 *Y 1<br/>Envitec Oxygen Sensors Design Input Device History Oxygen sensors Linearity &amp; Cross interference</p> <p>#21154 *Y 1 *BSI 8<br/>Envitec Oxygen Sensors Design Input Device History Design Input specifications</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------|-------------------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                   |       | <p>#17606 *J 1 *BSI 5<br/>Envitec Oxygen Sensors Location of responsibilities</p> <p>#15475 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (1) OOM103</p> <p>#15485 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (11) OOM110</p> <p>#15486 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (12) OOM111</p> <p>#15487 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (13) OOM112</p> <p>#15488 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (14) OOM201</p> <p>#15489 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (15) OOM202-1</p> <p>#15490 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (16) OOM203</p> <p>#15492 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (18) OOM 202-25</p> <p>#15493 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (19) OOM202-2</p> <p>#15494 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (20) OOM204</p> <p>#15481 *M 3.1 *BSI 3<br/>Envitec Oxygen Sensors OES (OEM) Specifications (7) OOM105</p> <p>#20115 *H 3 *BSI 13 *BSI 10<br/>Envitec Oxygen Sensors Post Market Surveillance</p> <p>#21619 *Z 2 *Y 15<br/>Envitec Oxygen Sensors QA Test Results Envitec Oxygen Sensors Validation Batch<br/>filed from gmail 2015-10-20</p> <p>#20850 *E 11 *E 3 *BSI 10</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------------|-------------------|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                   |       | <p>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#17611 *BSI 11.3 *Y 19<br/>Envitec Oxygen Sensors Software verification and validation reports and risk assessment EN 62304</p> <p>#14365 *M 3 *BSI 3<br/>Envitec Oxygen Sensors Specifications 0110042 Specification Datasheet v1.1</p> <p>#21613 *Y 15<br/>Envitec Oxygen Sensors Validation</p> <p>#21617 *Z 2 *Y 15<br/>Envitec Oxygen Sensors Validation Batch filed from gmail 2015-08-11</p> <p>#21615 *Z 2 *Y 15<br/>Envitec Oxygen Sensors Validation Batch filed from gmail 2015_2017</p> <p>#22872 *Y 15<br/>Envitec Oxygen Sensors Validation Oxygen sensors Linearity &amp; Cross Interference</p> <p>#7742<br/>Generic CE File Attached to All Assignment of responsibility Risk Management</p> <p>#22173<br/>Generic CE File Attached to All Risk management plan</p> <p>#16693 *F 6 *F 5 *BSI 14 *G 8<br/>Instructions for Use - Viamed Medical Oxygen Sensors</p> <p>#2557<br/>Management Responsibility Chart</p> <p>#14359 *M 3 *BSI 3<br/>Oxygen Sensors Specifications 0110071 Specification Datasheet v1.0</p> <p>#17618 *M 3 *BSI 3<br/>Specification Datasheet - 0110043</p> <p>#17620 *M 3 *BSI 3<br/>Specification Datasheet - 0110048</p> <p>#17622 *M 3 *BSI 3</p> |

| General Requirement | Applied Standards | Notes                                       | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------|-------------------|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                   |                                             | <p>Specification Datasheet - 0110049</p> <p>#15467 *F 5<br/>Vandagraph VST Sensors Instructions for Use User Manual</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> <p>#17423<br/>VM3COP02 Organisation Responsibilities Viamed</p> <p>#21556<br/>VM3COP02.02 Viamed Company Responsibilitys organisation chart structure</p> <p>#18763<br/>VM3COP02.1 Organisation Who`s Who VIAMED</p>                                                           |
| 2 ii                |                   | Design Drawings,label, Instructions For Use | <p>#22375<br/>CHART 35 Products On Market Risk Management Plan Post Market Surveillance</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#16693 *F 6 *F 5 *BSI 14 *G 8<br/>Instructions for Use - Viamed Medical Oxygen Sensors</p> <p>#15467 *F 5<br/>Vandagraph VST Sensors Instructions for Use User Manual</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> |

| General Requirement | Applied Standards | Notes                       | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------|-------------------|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2 iii               |                   | Internal Component.         | <p>#22375<br/>CHART 35 Products On Market Risk Management Plan Post Market Surveillance</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#16693 *F 6 *F 5 *BSI 14 *G 8<br/>Instructions for Use - Viamed Medical Oxygen Sensors</p> <p>#15467 *F 5<br/>Vandagraph VST Sensors Instructions for Use User Manual</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> |
| 2 iv                |                   | Label, Instructions For Use | <p>#22375<br/>CHART 35 Products On Market Risk Management Plan Post Market Surveillance</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#16693 *F 6 *F 5 *BSI 14 *G 8<br/>Instructions for Use - Viamed Medical Oxygen Sensors</p> <p>#15467 *F 5<br/>Vandagraph VST Sensors Instructions for Use User Manual</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------|-------------------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3                   | ISO 80601-2-55    |       | <p>#16320 *M 3 *BSI 3<br/>0110021 Specification Datasheet</p> <p>#12322 *BSI 3 *M 3<br/>0110023 Specification Datasheet</p> <p>#12328 *BSI 3 *M 3<br/>0110040 Specification Datasheet</p> <p>#12324 *M 3 *BSI 3<br/>0110044 Specification Datasheet</p> <p>#15142 *M 3 *BSI 3<br/>0110045 Oxygen Sensors Specifications R-45V datasheet</p> <p>#12326 *M 3 *BSI 3<br/>0110047 Specification Datasheet</p> <p>#9044 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation</p> <p>#1559 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 1</p> <p>#1560 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 2</p> <p>#1561 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 3</p> <p>#1562 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 4</p> <p>#1563 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 5</p> <p>#9043 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation Photos</p> <p>#20854 *H 3 *BSI 12<br/>Envitec Oxygen Sensors Clinical Evaluation CONFIDENTIAL FILES</p> <p>#20910 *BSI 10 *H 3 *BSI 13 *BSI 12<br/>Envitec Oxygen Sensors Clinical Trials Reports Reviews and Post Market</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------------|-------------------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                   |       | <p>Surveillance Clinical Evaluation</p> <p>#22868 *Y 1<br/>Envitec Oxygen Sensors Design Input Device History Oxygen sensors Linearity &amp; Cross interference</p> <p>#21154 *Y 1 *BSI 8<br/>Envitec Oxygen Sensors Design Input Device History Design Input specifications</p> <p>#20842 *BSI 11.1 *Z 3<br/>Envitec Oxygen Sensors External Test Results and Certificates ISO 80601-2-55<br/>CONFIDENTIAL FILES</p> <p>#22877 *M 1<br/>Envitec Oxygen Sensors Packaging Trials and validation Oxygen sensors Packaging</p> <p>#21150 *M 1 *BSI 20<br/>Envitec Oxygen Sensors Packaging Trials and validation Viamed</p> <p>#20115 *H 3 *BSI 13 *BSI 10<br/>Envitec Oxygen Sensors Post Market Surveillance</p> <p>#21619 *Z 2 *Y 15<br/>Envitec Oxygen Sensors QA Test Results Envitec Oxygen Sensors Validation Batch<br/>filed from gmail 2015-10-20</p> <p>#21540 *M 3<br/>Envitec Oxygen Sensors Specifications 001-05-<br/>Specification_Vandagraph_Ltd_OOI101-1-0</p> <p>#14367 *M 3<br/>Envitec Oxygen Sensors Specifications 0110021 Specification Datasheet v1.0</p> <p>#14365 *M 3 *BSI 3<br/>Envitec Oxygen Sensors Specifications 0110042 Specification Datasheet v1.1</p> <p>#21542 *M 3<br/>Envitec Oxygen Sensors Specifications 0110217 labelling artwork approval</p> <p>#21864 *M 3<br/>Envitec Oxygen Sensors Specifications 0110217 R-17VAN Specification datasheet<br/>v1.0 2017-08-24_06_09_17</p> <p>#15143 *M 3</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------|-------------------|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                   |       | <p>Envitec Oxygen Sensors Specifications Envitec OOM-106 datasheet</p> <p>#21698 *Y 18<br/>Envitec Oxygen Sensors Test and Design Reports mechanical strength</p> <p>#21613 *Y 15<br/>Envitec Oxygen Sensors Validation</p> <p>#21617 *Z 2 *Y 15<br/>Envitec Oxygen Sensors Validation Batch filed from gmail 2015-08-11</p> <p>#21615 *Z 2 *Y 15<br/>Envitec Oxygen Sensors Validation Batch filed from gmail 2015_2017</p> <p>#22872 *Y 15<br/>Envitec Oxygen Sensors Validation Oxygen sensors Linearity &amp; Cross Interference</p> <p>#14359 *M 3 *BSI 3<br/>Oxygen Sensors Specifications 0110071 Specification Datasheet v1.0</p> <p>#17618 *M 3 *BSI 3<br/>Specification Datasheet - 0110043</p> <p>#17620 *M 3 *BSI 3<br/>Specification Datasheet - 0110048</p> <p>#17622 *M 3 *BSI 3<br/>Specification Datasheet - 0110049</p> <p>#8106<br/>VM3COP18 Post Market Surveillance</p> <p>#17824<br/>VM3COP27.11 Performing a Technical File PMS and risk assessment</p> <p>#15453<br/>VM3COP27.12 Clinical Evaluation Risk assessment Technical Files</p> |

| General Requirement | Applied Standards                       | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------|-----------------------------------------|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4                   | EN ISO 14971:2012<br><br>ISO 80601-2-55 |       | <p>#20842 *BSI 11.1 *Z 3<br/>Envitec Oxygen Sensors External Test Results and Certificates ISO 80601-2-55<br/>CONFIDENTIAL FILES</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 5                   |                                         |       | <p>#9044 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation</p> <p>#1559 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 1</p> <p>#1560 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 2</p> <p>#1561 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 3</p> <p>#1562 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 4</p> <p>#1563 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 5</p> <p>#9043 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation Photos</p> <p>#17847 *T 2<br/>Envitec Oxygen Sensors Material Safety Data Sheet</p> <p>#21150 *M 1 *BSI 20<br/>Envitec Oxygen Sensors Packaging Trials and validation Viamed</p> <p>#17842 *T 2<br/>MSDS Viamed Oxygen Sensors</p> |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------|-------------------|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6                   |                   |       | <p>#20854 *H 3 *BSI 12<br/>Envitec Oxygen Sensors Clinical Evaluation CONFIDENTIAL FILES</p> <p>#20910 *BSI 10 *H 3 *BSI 13 *BSI 12<br/>Envitec Oxygen Sensors Clinical Trials Reports Reviews and Post Market Surveillance Clinical Evaluation</p> <p>#20115 *H 3 *BSI 13 *BSI 10<br/>Envitec Oxygen Sensors Post Market Surveillance</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File CONFIDENTIAL FILES</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> |
| 6 ii                |                   |       | <p>#20854 *H 3 *BSI 12<br/>Envitec Oxygen Sensors Clinical Evaluation CONFIDENTIAL FILES</p> <p>#20910 *BSI 10 *H 3 *BSI 13 *BSI 12<br/>Envitec Oxygen Sensors Clinical Trials Reports Reviews and Post Market Surveillance Clinical Evaluation</p>                                                                                                                                                                                                                                                                                                     |
| 7.1 i               |                   |       | <p>#20854 *H 3 *BSI 12<br/>Envitec Oxygen Sensors Clinical Evaluation CONFIDENTIAL FILES</p> <p>#20910 *BSI 10 *H 3 *BSI 13 *BSI 12<br/>Envitec Oxygen Sensors Clinical Trials Reports Reviews and Post Market Surveillance Clinical Evaluation</p>                                                                                                                                                                                                                                                                                                     |

| General Requirement | Applied Standards | Notes | Files                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------------|-------------------|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.1 ii              |                   |       | <p>#17847 *T 2<br/>Envitec Oxygen Sensors Material Safety Data Sheet</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#17842 *T 2<br/>MSDS Viamed Oxygen Sensors</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p>                                                                                              |
| 7.1 iii             |                   |       | <p>#17842 *T 2<br/>MSDS Viamed Oxygen Sensors</p>                                                                                                                                                                                                                                                                                                                                                                                        |
| 7.1 iv              |                   |       | <p>#20854 *H 3 *BSI 12<br/>Envitec Oxygen Sensors Clinical Evaluation CONFIDENTIAL FILES</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p>                                                                                                                                                                                                               |
| 7.2                 |                   |       | <p>#20854 *H 3 *BSI 12<br/>Envitec Oxygen Sensors Clinical Evaluation CONFIDENTIAL FILES</p> <p>#17847 *T 2<br/>Envitec Oxygen Sensors Material Safety Data Sheet</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#17842 *T 2<br/>MSDS Viamed Oxygen Sensors</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> |

| General Requirement | Applied Standards | Notes                                                                                                                                            | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.3                 |                   | Anaesthetic Gases                                                                                                                                | <p>#20842 *BSI 11.1 *Z 3<br/>Envitec Oxygen Sensors External Test Results and Certificates ISO 80601-2-55<br/>CONFIDENTIAL FILES</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p>                                                                                                                                                                                                                                                                            |
| 7.4                 |                   | No Drugs Included, No Materials Or Derivatives From Human Blood                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 7.5                 | EN ISO 14971:2012 | Risk Management File, Product Labelling, Safety Data Sheet, Instructions For Use. No Application Of Medicines, Body Liquids Or Other Substances. | <p>#20840 *D 1 *BSI 17<br/>Envitec Oxygen Sensors Classification rationale CONFIDENTIAL FILE</p> <p>#21146 *D 1 *BSI 17<br/>Envitec Oxygen Sensors Classification rationale Viamed</p> <p>#17847 *T 2<br/>Envitec Oxygen Sensors Material Safety Data Sheet</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#16693 *F 6 *F 5 *BSI 14 *G 8<br/>Instructions for Use - Viamed Medical Oxygen Sensors</p> <p>#17842 *T 2<br/>MSDS Viamed Oxygen Sensors</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> |

| General Requirement | Applied Standards | Notes                                     | Files                                                                                                                                                                                                                                                                                               |
|---------------------|-------------------|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.6                 |                   | Damage, Influence Of Disinfectants        | #20850 *E 11 *E 3 *BSI 10<br>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br>CONFIDENTIAL FILES<br><br>#20852 *BSI 10 *E 8 *E 3<br>Viamed`s Envitec Oxygen Sensors Risk Assesment                                                                                              |
| 8.1                 | EN ISO 14971:2012 | Risk Management File Instructions For Use | #20850 *E 11 *E 3 *BSI 10<br>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br>CONFIDENTIAL FILES<br><br>#16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors<br><br>#20852 *BSI 10 *E 8 *E 3<br>Viamed`s Envitec Oxygen Sensors Risk Assesment |
| 8.2                 |                   |                                           | #13135 *Z 10<br>No Animal Tissues No Animal Substances                                                                                                                                                                                                                                              |
| 8.3                 |                   | No Deliveries In Sterile State            |                                                                                                                                                                                                                                                                                                     |
| 8.4                 |                   | No Deliveries In Sterile State            |                                                                                                                                                                                                                                                                                                     |
| 8.5                 |                   | No Deliveries In Sterile State            |                                                                                                                                                                                                                                                                                                     |

| General Requirement | Applied Standards                       | Notes                                                              | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------|-----------------------------------------|--------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.6                 |                                         | No Deliveries In Sterile State                                     | <p>#9044 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation</p> <p>#1559 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 1</p> <p>#1560 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 2</p> <p>#1561 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 3</p> <p>#1562 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 4</p> <p>#1563 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation 5</p> <p>#9043 *M 1 *BSI 20<br/>Envitec Oxygen Sensor R-23V Packaging Trials and validation Photos</p> <p>#21150 *M 1 *BSI 20<br/>Envitec Oxygen Sensors Packaging Trials and validation Viamed</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> |
| 8.7                 |                                         | No Deliveries In Sterile State                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 9.1                 | EN ISO 14971:2012<br><br>ISO 80601-2-55 | Cross Reference List<br>(www.viamed.co.uk)<br>Instructions For Use | <p>#20899 *BSI 11.4<br/>Envitec Oxygen Sensors Evidence of Usability Human factors assessment</p> <p>#16693 *F 6 *F 5 *BSI 14 *G 8<br/>Instructions for Use - Viamed Medical Oxygen Sensors</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 9.2                 |                                         | Section Header                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 9.3                 |                                         | No, Limited Energy                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

| General Requirement | Applied Standards | Notes                               | Files                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------|-------------------|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.1                | ISO 80601-2-55    |                                     | <p>#16320 *M 3 *BSI 3<br/>0110021 Specification Datasheet</p> <p>#12322 *BSI 3 *M 3<br/>0110023 Specification Datasheet</p> <p>#12328 *BSI 3 *M 3<br/>0110040 Specification Datasheet</p> <p>#12324 *M 3 *BSI 3<br/>0110044 Specification Datasheet</p> <p>#15142 *M 3 *BSI 3<br/>0110045 Oxygen Sensors Specifications R-45V datasheet</p> <p>#12326 *M 3 *BSI 3<br/>0110047 Specification Datasheet</p> <p>#20842 *BSI 11.1 *Z 3<br/>Envitec Oxygen Sensors External Test Results and Certificates ISO 80601-2-55<br/>CONFIDENTIAL FILES</p> <p>#14367 *M 3<br/>Envitec Oxygen Sensors Specifications 0110021 Specification Datasheet v1.0</p> <p>#14365 *M 3 *BSI 3<br/>Envitec Oxygen Sensors Specifications 0110042 Specification Datasheet v1.1</p> <p>#15143 *M 3<br/>Envitec Oxygen Sensors Specifications Envitec OOM-106 datasheet</p> <p>#17618 *M 3 *BSI 3<br/>Specification Datasheet - 0110043</p> <p>#17620 *M 3 *BSI 3<br/>Specification Datasheet - 0110048</p> <p>#17622 *M 3 *BSI 3<br/>Specification Datasheet - 0110049</p> |
| 10.2                |                   | No,sensor Without Display Unit Only |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

| General Requirement | Applied Standards | Notes                                                   | Files |
|---------------------|-------------------|---------------------------------------------------------|-------|
| 10.3                |                   | No,sensor Without Display Unit Only                     |       |
| 11.1                |                   | No Radiation                                            |       |
| 11.2                |                   | No Radiation                                            |       |
| 11.2 i              |                   | No Radiation                                            |       |
| 11.2 2              |                   | No Radiation                                            |       |
| 11.3                |                   | No Radiation                                            |       |
| 11.3 1              |                   | No Radiation                                            |       |
| 11.4                |                   | No Radiation                                            |       |
| 11.4 1              |                   | No Radiation                                            |       |
| 11.5                |                   | No Ionizing Radiation                                   |       |
| 11.5 1              |                   | No Ionizing Radiation                                   |       |
| 11.5 2              |                   | No Ionizing Radiation                                   |       |
| 11.5 3              |                   | No Ionizing Radiation                                   |       |
| 12                  |                   | Section Header                                          |       |
| 12.1 i              |                   | No Electronic Programmable System                       |       |
| 12.1 ii             |                   |                                                         |       |
| 12.2                |                   | No Safety- Relevant Power Sources                       |       |
| 12.3                |                   | No Safety- Relevant Power Sources                       |       |
| 12.4                |                   | Sensor Measures Only Inspirational Oxygen Concentration |       |
| 12.5                |                   | Only Applicable In Connection With The Measuring Unit   |       |
| 12.6                |                   | Limited Energy Circuit                                  |       |

| General Requirement | Applied Standards | Notes                                                    | Files                                                                                                                                                                                                                                                                                                                                                                              |
|---------------------|-------------------|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 12.7                |                   |                                                          | <p>#20842 *BSI 11.1 *Z 3<br/>Envitec Oxygen Sensors External Test Results and Certificates ISO 80601-2-55<br/>CONFIDENTIAL FILES</p> <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p>                              |
| 12.7 1              |                   |                                                          |                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.7 2              |                   |                                                          |                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.7 3              |                   |                                                          |                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.7 4              |                   |                                                          |                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.7 5              |                   | Limited Energy                                           |                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.8                |                   | No Energy Supplies Or<br>Substances To Patients          |                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.8 1              |                   | No Energy Supplies Or<br>Substances To Patients          |                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.8 2              |                   | No Energy Supplies Or<br>Substances To Patients          |                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.9                |                   | Sensor Without Display<br>Unit Or User Interface<br>Only |                                                                                                                                                                                                                                                                                                                                                                                    |
| 13                  |                   |                                                          | <p>#20850 *E 11 *E 3 *BSI 10<br/>Envitec Oxygen Sensors Residual Risks Risk Management Master File<br/>CONFIDENTIAL FILES</p> <p>#17642 *F 7 *BSI 14<br/>Envitec Oxygen Sensors viamed Labels</p> <p>#16693 *F 6 *F 5 *BSI 14 *G 8<br/>Instructions for Use - Viamed Medical Oxygen Sensors</p> <p>#20852 *BSI 10 *E 8 *E 3<br/>Viamed`s Envitec Oxygen Sensors Risk Assesment</p> |

| General Requirement | Applied Standards      | Notes                        | Files                                                                                                                                                                                                                      |
|---------------------|------------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13.1                |                        |                              | #21923 *F 7<br>Envitec Oxygen Sensors Labels (Signed scan)<br><br>#17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels<br><br>#16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors |
| 13.2                | BS EN ISO 15223-1:2012 |                              | #21923 *F 7<br>Envitec Oxygen Sensors Labels (Signed scan)<br><br>#17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                              |
| 13.3                |                        |                              | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                                                                                                |
| 13.3 a              | BS EN ISO 15223-1:2012 | No Authorised Representative | #21923 *F 7<br>Envitec Oxygen Sensors Labels (Signed scan)<br><br>#17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                              |
| 13.3 b              | BS EN ISO 15223-1:2012 |                              | #21923 *F 7<br>Envitec Oxygen Sensors Labels (Signed scan)<br><br>#17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                              |
| 13.3 c              |                        | No Sterilisation             |                                                                                                                                                                                                                            |
| 13.3 d              |                        | Serial Number On Label       | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                                                                                                |

| General Requirement | Applied Standards      | Notes                                             | Files                                                                                                                                                    |
|---------------------|------------------------|---------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13.3 e              |                        | Regular Self Check And Calibration Of The Monitor |                                                                                                                                                          |
| 13.3 f              |                        | Not Single Use                                    |                                                                                                                                                          |
| 13.3 g              |                        | Not Custom Made                                   |                                                                                                                                                          |
| 13.3 h              |                        | Not For Clinical Investigations                   |                                                                                                                                                          |
| 13.3 i              |                        |                                                   | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                              |
| 13.3 j              |                        |                                                   | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                              |
| 13.3 k              |                        |                                                   | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                              |
| 13.3 l              | BS EN ISO 15223-1:2012 | Label Both On Product And Primary Packaging       | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                              |
| 13.3 m              |                        | Not Sterilized                                    |                                                                                                                                                          |
| 13.3 n              |                        | No Derivatives From Human Blood                   |                                                                                                                                                          |
| 13.4                |                        |                                                   | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels<br><br>#16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors |
| 13.5                |                        | SN On Label                                       | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                              |
| 13.6                |                        |                                                   |                                                                                                                                                          |

| General Requirement | Applied Standards | Notes                                                                                         | Files                                                                                                                                                                                                                                                                             |
|---------------------|-------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13.6 a              |                   |                                                                                               | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels                                                                                                                                                                                                                       |
| 13.6 b              |                   | Reference In Instructions<br>For Use And Technical<br>Data Sheet                              | #17847 *T 2<br>Envitec Oxygen Sensors Material Safety Data Sheet<br><br>#17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels<br><br>#16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors<br><br>#17842 *T 2<br>MSDS Viamed Oxygen Sensors |
| 13.6 c              |                   | Reference In Instructions<br>For Use With Link To<br>Cross Reference List<br>Www.viamed.co.uk | #16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors                                                                                                                                                                                             |
| 13.6 d              |                   | IFU Of The Equipment<br>Should Be Used                                                        | #16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors                                                                                                                                                                                             |
| 13.6 e              |                   | No Implantable Product                                                                        |                                                                                                                                                                                                                                                                                   |
| 13.6 f              |                   |                                                                                               |                                                                                                                                                                                                                                                                                   |
| 13.6 g              |                   | Not Sterile                                                                                   |                                                                                                                                                                                                                                                                                   |
| 13.6 h              |                   | IFU And IFU Of The<br>Main Equipment Should<br>Be Usednot Sterile                             | #16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors                                                                                                                                                                                             |
| 13.6 i              |                   |                                                                                               | #16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors                                                                                                                                                                                             |
| 13.6 j              |                   | No Radiation                                                                                  |                                                                                                                                                                                                                                                                                   |
| 13.6 k              |                   |                                                                                               |                                                                                                                                                                                                                                                                                   |
| 13.6 l              |                   |                                                                                               |                                                                                                                                                                                                                                                                                   |
| 13.6 m              |                   | No Medicines                                                                                  |                                                                                                                                                                                                                                                                                   |

| General Requirement | Applied Standards | Notes                             | Files                                                                                                                                                                                                     |
|---------------------|-------------------|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13.6 n              |                   | We Offer Special Disposal Service | #17642 *F 7 *BSI 14<br>Envitec Oxygen Sensors viamed Labels<br><br>#16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors<br><br>#17842 *T 2<br>MSDS Viamed Oxygen Sensors |
| 13.6 o              |                   | No Derivatives, No Human Blood    |                                                                                                                                                                                                           |
| 13.6 p              |                   | No Measuring Function             |                                                                                                                                                                                                           |
| 13.6 q              |                   |                                   | #16693 *F 6 *F 5 *BSI 14 *G 8<br>Instructions for Use - Viamed Medical Oxygen Sensors                                                                                                                     |