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Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016

BOUNDRIES/EXCLUSIONS to SYSTEM

Version Date: 10 Nov 2021

Listing of Current Sections

Section	Reason for Exclusion
6 Contamination control	**[6.4.2] Contamination control** **Not Applicable in relation to sterile products** **Viamed does not have any Sterile** **Products,**
6.4.2 As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes. **Contamination control**	**[6.4.2] Contamination control** **Not Applicable in relation to sterile products** **Viamed does not have any Sterile** **Products,** **Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID69688 Date Revision 14 Sep 2021 Reviewed 14 Sep 2021 **Top Level Document: VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection** Revision Document ID73779 Date Revision 02 Nov 2021 Reviewed 02 Nov 2021 **Top Level Document: VOP 09 Repairs and Servicing**

	Revision Document ID68239 Date Revision 26 Aug 2021 Reviewed 26 Aug 2021
# 7 Design and development	**[7.3] Design and development** **Excluded while MDR settles in, And Viamed has No production of any Medical Devices**
7.3 **Design and development**	**[7.3] Design and development** **Excluded while MDR settles in, And Viamed has No production of any Medical Devices**
7.5.3 The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5). **Installation activities**	**No More Installation activitys** **Resuscitation Unit and TC400 Maintenance TC400 Installation Instructions** Revision Document ID8155 Date Revision 24 Mar 2011 Reviewed 24 Mar 2011 **Resuscitation Unit Instructions for Use / Installation Ceratherm v3.01 Resuscitation Unit and TC400 Maintenance** Revision Document ID8178 Date Revision 24 Mar 2011 Reviewed 24 Mar 2011 **Resuscitation Unit Instructions for Use / User Manual Nufer Wall Mount Installation** Revision Document ID1312 Date Revision 19 Mar 2007 Reviewed 19 Mar 2007 **VM3COP51.20 Resuscitation Cabinet Installation Instructions** Revision Document ID18221 Date Revision 12 Dec 2016 Reviewed 12 Dec 2016 **Audit 24 Service Logs** Revision Document ID68263 Date Revision 26 Aug 2021 Reviewed 26 Aug 2021
7.5.5 The organization shall maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices. **Particular requirements for sterile medical devices**	**Viamed does not have any Sterile Products,** **Not Appllicable**

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7.5.7 The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems. Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate. Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5). NOTE Further information can be found in ISO 11607-1 and ISO 11607-2. **Particular requirements for validation of processes for sterilization and sterile barrier systems**	**Viamed does not have any Sterile Products,** **Not Appllicable** **Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID69688 Date Revision 14 Sep 2021 Reviewed 14 Sep 2021
7.5.9.2 The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements. The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5). **Particular requirements for implantable medical devices**	**[7.5.9.2]** **Viamed does not have any implantable medical devices Not Applicable.** **Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID69688 Date Revision 14 Sep 2021 Reviewed 14 Sep 2021