Boundaries of 13485:2016:

6.4.2 **Contamination control**

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.

Justification:
Viamed does not have any Sterile Products,

7.5.5 **Particular requirements for sterile medical devices**

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.

Justification:
Viamed does not have any Sterile Products,

7.5.7 **Particular requirements for validation of processes for sterilization and sterile barrier systems**

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.

Justification:
Viamed does not have any Sterile Products,

7.5.9.2 **Particular requirements for implantable medical devices**

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

Justification:
Viamed does not have any implantable devices,