

Introduction:

All Medical products require a CE mark and an accompanying Technical file
Each product has its own unique file

Viamed CE files all take the same format:

Red Binder sectioned A-Z.
Red ducket for current un-filed data
Intrastats CE Files
Paperport Documentation centre

Red Binders:

These binders are sectioned A-Z where each letter is a major subject or group of associated subjects. The sections are sub-sectioned to reduce the number of documents in any single section. Over time more subsections can be added.

e.g.

[D] Classification
D1 product classification
D2 Device classification rules
D3 Flow charts
D4 EMC classification

Red Duckets.

Vast quantities of information mainly during the design phase are received sometimes with no obvious specific designated area.

These documents are held in a Red ducket. These duckets are also used for product development ideas prior to adoption.

Supplier files also contain hard copies of technical correspondence.

With the advent of email this correspondence and meeting minutes are also held in “Goldmine”, an electronic filing and contact system. When it is felt necessary hard copies are made and kept in the project or CE file

Written procedures are compiled in Word documents or Open office

Current location path is Drive S: CEMARK / Product Name / Document

This can be located with a normal Windows search.

Paperport

All hard copy documents are scanned into “Paperport”, an electronic document filing system. All Word, Word pro documents, and “Goldmine” documents are printed into paperport.

Non-Viamed products have CE files/Technical where possible and OEM's are encouraged to supply as much information as possible, which is scanned into Paperport as well as hard copy.