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
Paperport

Red Binders:
These binders are sectioned A-Z where each letter is a major subject or group of associated subjects
e.g.

[D]   Classification
        Has both product classification and EMC classification

[F] Device description
        Includes Device description, Literature, Accessories, Instructions labels.
Where the files are large these sections may be split numerically

Red Duckets.
Vast quantities of information mainly during the design phase are received sometimes with no 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.

Written procedures are compiled in Word documents.
Current location path is Drive T:
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 where possible and OEM's are encouraged to supply as much information as possible, which is scanned into Paperport as well as hard copy.