

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.  
They can be located with a normal Windows search.

Common Files are in use for specific families of products i.e. Plastics, Pulse Oximetry

Paperport

All hard copy documents are scanned into “Paperport” and 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.