
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. Y & Z are the Design Input & Design Output files

These paper documents should be scanned then added into the Red Binder in the appropriate section.

Paperport is the current electronic documentation software being used.

CE Files electronically stored in “Intrastats will replace Paperport as a live collection system and leave Paperport as an archiving system and a platform for viewing large numbers of documents simultaneously.

Red Binders:

These binders are sectioned A-Z where each letter is a major subject or group of associated subjects

Letters may be sub divided with numbered categories

e.g. Section D Classification sections D2 Classification rules & D3 Flow charts are common to all CE Files

D1 product classification

D4 EMC Rationale

D5 EMC report

D6 Safety report

EMC classification

Some sections are becoming obsolete as much information is now transferred electronically.

Red Duckets.

Red duckets are for current un-filed data. Data can accumulate in the form of letters, faxes, & Data sheets. 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.

Suppliers files may 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 systems.

Written procedures are compiled in Word Pro , Word docISO and CE working

files. Company/Cemark/ Product name?/ Document

This can be located with a normal Windows search.

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.

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