NO.	Category	Condition	Prescription	備　註 (說明)
1	品質手冊 Quality manual	DIVA 文件 DIVA owned	每一版都保存做為比對 Reserve each version for comparison	4.2.4 文件管制 公司應至少保存一份作廢的文件，並確定其保存期限。 這個期限應確保至少在公司所規定的醫療器材壽命期內，可以得到此醫療器材的製造和試驗的文件。
2	程序文件 Procedure	DIVA 文件 DIVA owned	每一版都保存做為比對 Reserve each version for comparison	
3	標準作業程序/標準檢驗程序/作業指導書 SOP / SIP/ WI	設計文件 Use for design	1. 每一版都保留到服務期限終止，或 2.依客戶要求(若客戶要求期限比服務期限長) 1. Each version should be reserved till EOS (end of service) of production, or 2. Bases on customer's requirement (if customer's requirement is longer than EOS)	
		製造生產流程 Use for production	1. 每一版保留到服務期限終止，或 2.依客戶要求(若客戶要求期限比服務期限長) 1. Each version should be reserved till EOS (end of service) of production, or 2. Bases on customer's requirement (if customer's requirement is longer than EOS)	
4	記錄/報告/表單 Record/ Report/ Form	設計文件 Use for design	1. 保留到服務期限終止，或 2.依客戶要求(若客戶要求期限比服務期限長) 1. Till EOS (end of service) of production, or 2. Bases on customer's requirement (if customer's requirement is longer than EOS)	如果表單/報告上的資料也同時被留存在ERP系統或公司伺服器上的e化的電子文件時，選擇相對可以被安全、簡單留存較長的其一保留之。 If the date on record/ report/ form is also represented in ERP system or e-file in server, choose one of them which is easier and can be reserve more safe and longer.
		製造生產流程 Use for production	1. 保留到產品壽命(依RD設計值)終止，或 2.依客戶要求(若客戶要求比產品壽命長) 1. Till EOL (end of life designed by RD) of production, or 2. Bases on customer's requirement (if customer's requirement is longer than EOL)	
		一般行政使用 Use for general	1年 (1 year)	
5	材料規格書/ 圖面 Data Sheet/ Drawing	DIVA 文件 DIVA owned	1. 每一版都保留到使用讓材料之產品服務期限終止，或 2.依客戶要求(若客戶要求期限比服務期限長) 1. Each version should be reserved till EOS (end of service) of production which use such material, or 2. Bases on customer's requirement (if customer's requirement is longer than	
		客戶財產 Customer owned	依客戶要求並在作廢前得到客戶確認 Base on customer 's requirement and get customer's approval before scrap	
6	稽核和管理審查 Audit & Management review	DIVA 文件 DIVA owned	3年 (3 years)	
8	國際標準/ 法規 International STD,/ Regulation	國際文件 International Std.	即時更新並保存一份舊標準 Renew immidiately and reserve previous version	EU/ CE: reserve for 10 years TW GMP: reserve for 3 years
		儀器設備文件 Instrument or equipment	即時更新並保存一份舊標準 Renew immidiately and reserve previous version	

9	外來文件 Document from	國際標準檢驗規範 International inspection STD. (IIS)	1. 每一版保留到服務期限終止，或 2.依客戶要求(若客戶要求期限比服務期限長) 1. Each version should be reserved till EOS (end of service) of production, or 2. Bases on customer's requirement (if customer's requirement is longer than	
10	RoHS/REACH符合性聲明和相關禁限用物質技術檔及檢驗紀錄 RoHS/ REACH test report, record or compliance claiming	DIVA 文件 DIVA owned	產品投放市場後需要保存10年 Reserve for 10 yeasrs after product hits to shelves	
11	員工資料 HR information and data	DIVA 文件 DIVA owned	1.員工離職後保留5年(教育訓練記錄) Reserve for 5 years after employee resigned. 2.保留5年(其他) (Other 5 years)	
12	第三方認證報告 3rd party ertification data	DIVA 文件 DIVA owned	認證有效日到期後1年 Reserve for 1 year after the certification expires	
13	中國3C之品質記錄 China 3C relevant data	DIVA 文件 DIVA owned	1. 保留到產品壽命(依RD設計值)終止，或 2.依客戶要求(若客戶要求比產品壽命長) 1. Till EOL (end of life designed by RD) of production, or 2. Bases on customer's requirement (if customer's requirement is longer than EOL)	