

Device Master Record (DMR)

Project/Product

Document number, version, date

The Device master record as per 21CFR820.181 is contained within the technical file as per SOP Technical File. The DMR therefore refers to the location of the information needed.

	Content DMR	Location / Reference
(a) Device specifications including ...	appropriate drawings	
	Composition and formulation	
	component specifications	
	software specifications	
(b) Production process specifications including...	appropriate equipment specifications	
	production methods and production procedures	
	production environment specifications	
(c)	Quality assurance procedures and specifications Including acceptance criteria and quality assurance equipment	
(d)	Packaging and labeling specifications including methods and processes used	
(e)	Installation, maintenance, and servicing procedures and methods	

Approval

name / date / signature

name / date / signature