

**Example* of Technical Documentation for In Vitro Diagnostic Medical Devices
(Annex III - IVDD 98/79/EC)**

**This is a draft document only! Manufacturers should review and apply the requirements of the IVDD 98/79EC accordingly to their technical documentation. MDSS accepts no responsibility or liability whatsoever with regard to the material provided in this document.*

- A** Assists
- R** Responsible
- P** Preparation
- V** Voluntary

		Research/Design & Development Management/QMS Representative	Production/Manufacturing	Sales & Marketing/Shipping	Notified Body
1	Manufacturer Information				
1.1	Name and address of Manufacturer , name and address of Authorized Representative, all manufacturing locations, (excerpt commercial register or trading license)	RP			
1.2	Manufacturer's EC Declaration of Conformity, Application or certificates, documentation Quality System EN ISO 13485	RP			A
1.3	DIMDI Notification according to §§ 25 and 31 MPG and Art. 10 of the Directive 98/79/EC. Form for certification information of IVD (Annex III to VII of 98/79/EC)	RP			
2	Product Description				
2.1	Product description including all variations (photographs, advertising material or brochure) as well as a clear definition of the product and its accessories.	R	A	P	
2.2	Definition of Intended Use		RP	A	
2.3	Classification and Conformity assessment procedure according to IVDD 98/79/EC.	R	P		
2.4	Documents delivered/distributed with product: instructions for use, user manuals, (EN 591, EN 592), installation instructions, service documents, and maintenance instructions.	R	A	P	
2.5	Labeling and Information				
	• Labeling of and product information on the IVD product provided to professional users (EN 375)	R	A	P	
	• Labeling of and product information on the IVD product provided for use of product by lay persons (EN 376, EN 13532)	R	A	P	
	• Labeling requirements for IVD Instruments (EN 1658)	R	A	P	
	• Model/makes/serial plates or labels, warnings, symbols used (EN 980, ISO 15223)	R	A	P	

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2.6		List of standards applied, of Common Technical Specifications (CTS) and proof of fulfillment of essential requirements (CE essential requirement checklist)	R	P		
2.7		Risk analysis and hazard management processes (EN ISO 14971, EN 61010-1-x, EN 13641), including graphs and summary of the risk analysis. Software security	RA	P		A
2.8		Specified combinations with other products (product compatibility), module interfaces		RP		A
3		Product specifications				
3.1		List of components, instrument and assembly identification, parts list with manufacturer's data		R	A	
3.2		Device and Component Design: mechanical design, component diagram, circuit/wiring diagram, parts list with approximate X,Y position, electrical layout all layers, instrument assembly instructions, terminal allocation plan/diagram.		RP	A	
3.3		Description of components, circuits and functions, alarm scheme, insulation diagram.		RP	A	
3.4		Biological and chemical specifications of components		RP	A	
3.5		Specifications of other material used		RP	A	
3.6		Specifications of substances to be used in reagent/instrument combination		RP	A	
3.7		Description of manufacturing procedure, of process validation procedure, of specifications during manufacturing, for example, clean room requirement, production hygiene, of programmer description, instruction/references for distributor/shipping, operation breakdown sheet (including startup/initiation plan), procedure and processes		RP	A	
3.8		Production quality assurance measures (inspection plan & procedure, descriptions of in-process verification and final inspection. Sample of test reports		RP	A	A
3.9		Description of sterilization specifications (EN 552, EN 556) and environment hygiene, process validation		RP	A	
3.10		Packaging specifications (EN 868-x, EN 829)		RP		A

