F29A Minimal Requirements for Technical Files of Medical Devices

1/ IDENTIFICATION DATA
Name and address of Manufacturer
Name and address of Notified Body
Certificates
Medical Device (MD) Classification
Conformity assessment procedure
Internationally recognized nomenclature code of MD (GMDN or UMDNS or EDMA)
2/ GENERAL DESCRIPTION OF MD
Description
Intended use
Main mode of action
Composition of MD
Components or accessories of MD/ kit
Shelf-life
Storage and stability of the product / materials / reagents
Principle of the assay or test or function
Assay and results / Testing procedure
Criteria of acceptability of the test results
Evaluation and interpretation of results
Assay and results / Testing procedure – sensitivity, specificity, reproducibility, stability, etc.
Limits and side effects
Drawings, description and necessary explanation on the drawings
Description of sterilization methods, if MD is placed on the market or put into service in sterile condition
3/ STANDARDS APPLIED
List of the applied standards
4/ ESSENTIAL REQUIREMENTS
Check list according to Annex I of MDD No.93/42/EEC as amended and IVD MDD No.98/79/EC as amended
5/ RISK ANALYSIS AND RISK MANAGEMENT
Application of the risk management to MD according to EN ISO 14971
6/ PRE-CLINICAL EVALUATION (with respect to EN ISO 10993) AND CLINICAL EVALUATION (for MD with respect to ISO 14155 and MEDDEV 2.7.1)
Note: In the case of IVDs, investigations in a clinical environment are described as “Performance evaluation studies”
7/ DOCUMENTATION LIST
Label of MD
Package insert
Technical sheet of MD
Material Safety data sheet
8/ PROJECT DESCRIPTION
History of MD
Complaints from customers

9/ DETAILED RAW MATERIAL LIST
Strategic raw materials / reagents
Materials of animal / human origin
Information on substances and dangerous materials
List of critical suppliers
10/ SPECIFICATIONS OF MD
11/ COMPATIBILITY WITH OTHER MDs
12/ EVALUATION RESULTS
Electric safety, EMC, biochemical performances, toxicity studies, biocompatibility, etc.
13/ STABILITY DATA
Accelerated ageing (if applicable)
14/ PRODUCTION DOCUMENTS
Method of production and standards
Validation of the manufacturing processes (software, sterilization, clean-room, packaging, etc.)
List of the equipment
Maintenance program
15/ QUALITY SYSTEM DOCUMENTS
Control of production
Equipment
Maintenance
Working environment and infrastructure
Documentation and sampling
The methods for monitoring efficient operation of the quality system and in particular the type and extent of controls applied to external providers (critical suppliers) in relation to manufactured MD
IFU – Instructions for Use
16/ EC DECLARATION OF CONFORMITY
Draft of EC Declaration of Conformity prepared by manufacturer
Agreement with European Representative
17/ DECLARATION OF AGREEMENT WITH NOTIFIED BODY
18/ POST - MARKET SURVEILLANCE (PMS)
Post-market surveillance
MDs vigilance system (see MEDDEV 2.12)