European Association
Notified Bodies Medical Devices

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Medical Device Notified Body Recommendations List

Below is a list of Recommendations of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC : (updated 08/04/2009)

Issue	Date or status	Recommendation Title
NB-MED/2.1/Rec1	Stage 3 6 & 7/06/2000	Representative sample
NB-MED/2.1/Rec2	Stage 4. 9 & 10/02/1998	Explanation of Terms
NB-MED/2.1./Rec2	Stage 4. 9 & 10/02/1998	Product-Device-Range-Category
NB-MED/2.1/Rec3 *(3)*	No information in the document	Accessories and other parts for Active Implantable Medical devices
NB-MED/2.1/Rec4	OBSOLETE	Medical Devices with a measuring function **superseded Meddev 2.1/5** (11.06.98)
NB-MED/2.1/Rec5	Stage 3 6 & 7/06/2000	Placing on the market of fully refurbished medical devices
NB-MED/2.2/Rec1 *(3)*		EMC requirements
NB-MED/2.2/Rec2	Stage 3 29/02& 1/03/2000	Treatment of computer used to program implantable pulse generators
NB-MED/2.2/Rec3	Stage 3 6 & 7/06/2000	"Use-by" date for Medical devices
NB-MED/2.2/Rec4	Stage 3 06.11.2001	Software and Medical devices
NB-MED/2.2/Rec5	NEW! *Adopted by the 40th meeting of NB-Med, 31/03&1/04/2009*	Machinery Directive's Essential Health and Safety Requirements (EHSR) relevant for Medical Devices
NB-MED/2.5.1/Rec4	Stage 3 8 & 9/06/1999	Content of mandatory certificates
NB-MED/2.5.1/Rec5 *(3)*	Stage 3 29/02& 1/03/2000	Technical Documentation
NB-MED/2.5.1/Rec6 *(3)*	Stage 3 7 & 8/11/2000	Renewal of EC Design-Examination and Type-Examination Certificates
NB-MED/2.5.2/Rec1 *(3)*	Stage 3 29/02& 1/03/2000	Subcontracting - QS related
NB-MED/2.5.2/Rec2	Rev 8, 25& 26/11/2008	Reporting of design changes and changes of the quality system
NB-MED/2.5.2/Rec3 *(3)*	Stage 3 29/02& 1/03/2000	Translation procedure
NB-MED/2.5.4/Rec1 *(3)*	Stage 3 29/02& 1/03/2000	Homogeneous batches
NB-MED/2.5.4/Rec2	Stage 3 6 & 7/06/2000	Verification of Manufactured Products for the IVDD

NB-MED/2.5.5/Rec1	OBSOLETE	Conformity assessment procedures of breast implants **superseded by Meddev 2.5/6** (07/98)
NB-MED/2.5.5/Rec2	Stage 3 6 & 7/03/2001	Combination of CE-marked and non-CE-marked medical devices and non-medical devices
NB-MED/2.5.5/Rec3	Stage 3 6 & 7/06/2000	Conformity Assessment of Annex II, IVD's designed and evaluated prior to adoption of Common Technical Specifications (CTS)
NB-MED/2.5.5/Rec4	Stage 3 6 & 7/03/2001	Assessment of the sensitivity of In Vitro Diagnostic Medical Devices - guidance on the application of the CTS
NB-MED/2.5.5/Rec2-	NBRG draft 13/11/2006	Conformity assessment procedures for hip, knee and shoulder total joint replacements
NB-MED/2.5.5/Rec5	NBRG draft 04/2006	Conformity Assessment of Own Brand Labelling
NB-MED/2.7/Rec1	Stage 4. 9 & 10/06/1998	Guidance on clinical
NB-MED/2.7/Rec3	Stage 4. 8 & 9/06/1999	Evaluation of clinical data
NB-MED/2.9 Rec 1	NEW! *31/03&1/04/2009*	Procedure packs, application of Art 11 or Art 12
NB-MED/2.12/Rec1	Stage 3 29/02& 1/03/2000	Post-Marketing Surveillance (PMS) post market/production
NB-MED/2.13/Rec1	Stage 4. 9 & 10/02/1998	CE Marking of pre-MDD Devices
NB-MED/2.13/Rec2	Stage 3 6 & 7/06/2000	CE Marking of established IVD Devices
NB-MED/2.15/	Stage 3 6 & 7/06/2000	Voluntary certification at an intermediate stage of manufacture
???		Vigilance_Recommendation_after NB-Med_2007-04