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Terminology – Glossary – Definitions

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TERMS	DEFINITIONS
Medical Device:	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: • diagnosis, prevention, monitoring, treatment or alleviation of disease, • diagnosis, monitoring, treatment, alleviation of or compensation for an injury, • investigation, replacement, modification, or support of the anatomy or of a physiological process, • supporting or sustaining life, • control of conception, • disinfection of medical devices, • providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.
	Note: Products which may be considered to be medical devices in some jurisdictions but not in others include: • disinfection substances, • aids for persons with disabilities, • devices incorporating animal and/or human tissues, • devices for.in-vitro fertilization or assisted reproduction technologies.

TERMS	DEFINITIONS
Active medical device:	Medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy.
In Vitro Diagnostic (IVD) Medical Device:	A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. Note 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status. Note2: In some jurisdictions, certain IVD medical devices may be covered by other regulations

TERMS	DEFINITIONS
Manufacturer:	Natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party
Conformity Assessment:	The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance for Medical Devices.
Labelling:	The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

TERMS	DEFINITIONS
Clinical evaluation:	The assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device.
Clinical Data:	Safety and/or performance information that are generated from the clinical use of a medical device.
Clinical Data: MDD, art 1	The information concerning the safety or performance that is generated from the use of a device and that are sourced from the following: – clinical investigation(s) of the device concerned, – clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, – published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;

TERMS	DEFINITIONS
Clinical Performance:	The ability of a medical device to achieve its intended purpose as claimed by the manufacturer.
Clinical Investigation:	Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device.
Clinical Evidence:	The clinical data and the clinical evaluation report pertaining to a medical device.

TERMS	DEFINITIONS
Risk analysis:	Systematic use of available information to identify hazards and to estimate the risk
Life-cycle:	All phases in the life of a medical device, from the initial conception to final decommissioning and disposal

TERMS	DEFINITIONS
'nanomaterial' 2012/0266 (COD)	means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials. For the purposes of the definition of nanomaterial, 'particle', 'agglomerate' and 'aggregate' are defined as follows: – 'particle' means a minute piece of matter with defined physical boundaries; – 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components; – 'aggregate' means a particle comprising of strongly bound or fused particles;

TERMS	DEFINITIONS
CA - Competent Authority	Organization which has the authority to act on behalf of the government of a Member state to ensure that the requirements of the Directives are carried out in a particular Member State. The role of the Competent Authority is determined by the Directives and associated National Regulations. Its prime aim is to ensure that all medical devices meet the essential requirements laid down in the Directives.
NB - Notified Body	Recognised third party bodies that can carry out a conformity assessments laid down in the relevant harmonised European standards or European Technical Assessment. The range of possible notifiable tasks are: - product certification; - factory production control (FPC) certification; - determination of the product-type on the basis of type testing.
FDA	Food and Drug Administration

TERMS	DEFINITIONS
Premarket Approval (PMA)	A premarket approval means any premarket approval application for a Class III medical device, including all information submitted with or incorporated by reference therein. (21 CFR 814.3)
	FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
Premarket Notification [PMN or 510(k)]	510(k) refers to the type of submission to FDA described under 21 CFR 807 Subpart E in which the applicant must establish that their device is substantially equivalent to a legally marketed device. This type of submission is used for most Class II devices and some Class I devices.

TERMS	DEFINITIONS
Quality Management System (QMS):	Management system to direct and control an organization with regard to quality.
Technical Documentation:	The documented evidence, normally an output of the quality management system, which demonstrates conformity of a device to the Essential Principles of Safety and Performance of Medical Devices (SG1/N041)
Post market surveillance	Systematic process to collect and analyze experience gained from medical devices in the post-production phase

REFERENCES	
Guidance MEDDEVs:	Commission Guideline relating to medical devices directives - the MEDDEV aim at promoting a common approach by Member States, manufacturers and Notified Bodies and are carefully drafted through a process of consultation with various interested partie.
IMDRF:	International Medical Device Regulators Forum ex: Global Harmonization Task Force
GHTF/SC/N4:2012 (Edition 2)	Glossary and Definitions of Terms Used in GHTF Documents
Medical Devices - Acronyms	http://ec.europa.eu/health/medical-devices/acronyms/index_en.htm
New Approach Standardisation in the Internal Market	http://www.newapproach.org/Directives/DirectiveList.asp

Tools	Ref
FDA - Recognized Consensus Standards	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

European Commission

PUBLIC HEALTH

European Commission > DG Health and Food Safety > Public health > Medical devices > Documents > Guidelines

MEDICAL DEVICES

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Guidance MEDDEVs

The guidelines aim at promoting a common approach by manufacturers and Notified Bodies involved in the conformity assessment procedures according to the relevant annexes of the Directives, and by the Competent Authorities charged with safeguarding Public Health.

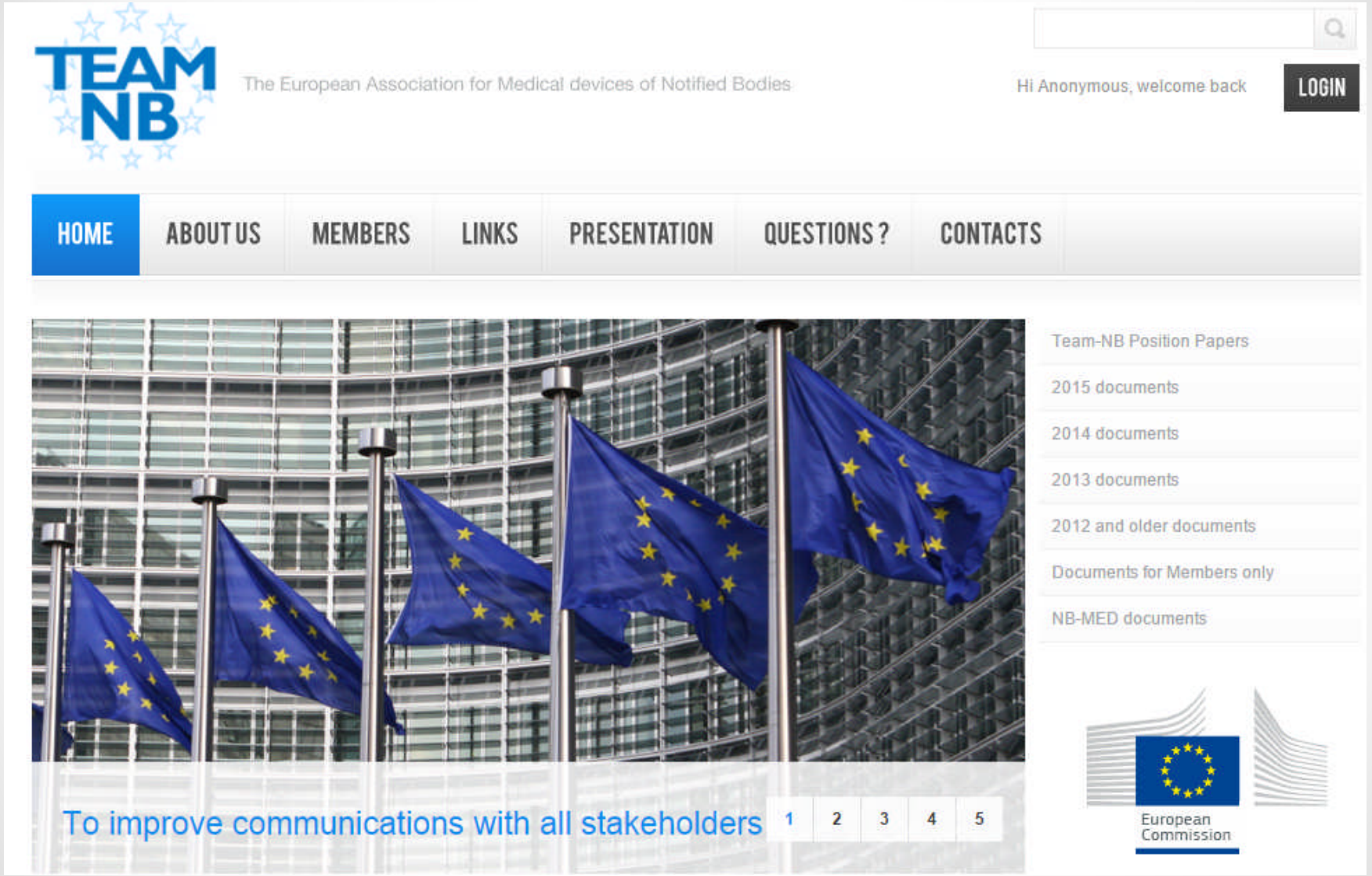
They have been carefully drafted through a process of consultation with various interested parties during which intermediate drafts were circulated and comments were taken up in the documents. Therefore, they reflect positions taken in particular by representatives of Competent Authorities and Commission Services, Notified Bodies, industry and other interested parties in the medical devices sector.

The guidelines are not legally binding. It is recognised that under given circumstances, for example, as a result of scientific developments, an alternative approach may be possible or appropriate to comply with the legal requirements.

Due to the participation of the aforementioned interested parties and of experts from Competent Authorities, it is anticipated that the guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions. Guidelines are subject of a regular updating process.

Disclaimer : Please note that the amendments introduced by Directive 2007/47/EC or previous amending directives have not yet been incorporated in all MEDDEVs. The necessary revision is under way.

	TITLE
2.1 Scope, field of application, definition	MEDDEV 2.1/1 (19 KB) Definitions of "medical devices", "accessory" and "manufacturer" **April 1994**
	MEDDEV 2.1/2 rev.2 (14 KB) Field of application of directive "active implantable medical devices" **April 1994**


TEAM NB
The European Association for Medical devices of Notified Bodies
Hi Anonymous, welcome back
LOGIN
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ABOUT US
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LINKS
PRESENTATION
QUESTIONS ?
CONTACTS
Team-NB Position Papers
2015 documents
2014 documents
2013 documents
2012 and older documents
Documents for Members only
NB-MED documents
To improve communications with all stakeholders
1
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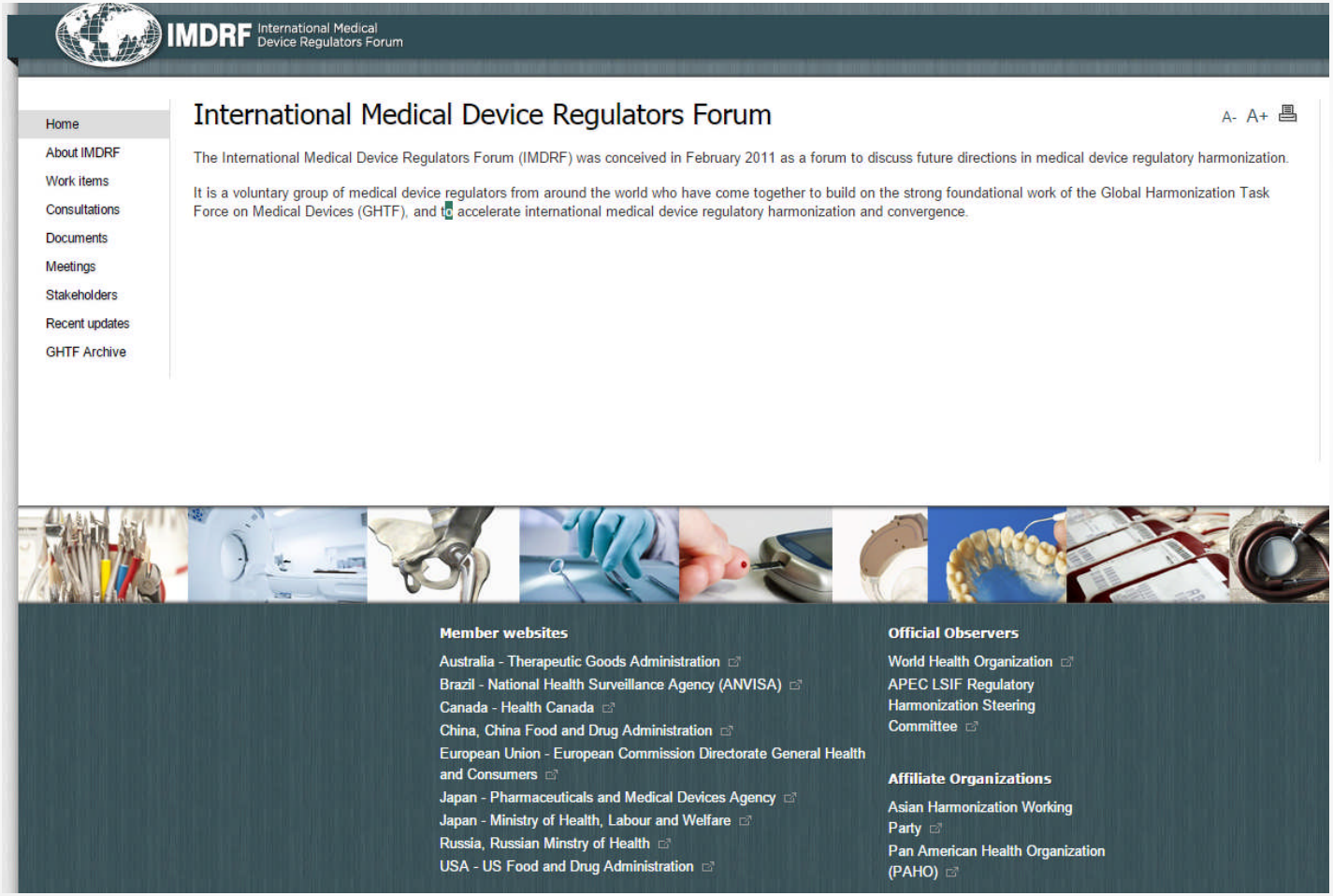
European Commission


IMDRF International Medical Device Regulators Forum
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International Medical Device Regulators Forum
A- A+
The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.
It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.
Member websites
Australia - Therapeutic Goods Administration
Brazil - National Health Surveillance Agency (ANVISA)
Canada - Health Canada
China, China Food and Drug Administration
European Union - European Commission Directorate General Health and Consumers
Japan - Pharmaceuticals and Medical Devices Agency
Japan - Ministry of Health, Labour and Welfare
Russia, Russian Minstry of Health
USA - US Food and Drug Administration
Official Observers
World Health Organization
APEC LSIF Regulatory Harmonization Steering Committee
Affiliate Organizations
Asian Harmonization Working Party
Pan American Health Organization (PAHO)