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Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessments

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1 Introduction

NANDO [1], published and maintained by the European Commission, is an electronic register that enables interested parties to consult regulatory information of Notified Bodies (NBs). The NANDO register contains scope information of Notified Bodies under the New Approach Directives. Up to now the information provided by Member States is not precise enough to allow the comparisons necessary to promote a free competition between Notified Bodies in the medical devises area.

In particular in the medical devices sector, identical designation information appears in the register in a broad variation between NBs. Different Designating Authorities (DAs) use different expressions when they sign up for designation of their NBs. In some Member States (MS) the DAs submit the designation information, the so-called scope, by just take reference to one of the medical devices directives. Other MS try to define and submit a detailed scope according to the existing and monitored competence of their NBs. This can end up in very exhaustive information per directive and NB.

The NANDO information provided to interested users like manufacturers, Designating Authorities and Authorities responsible for market surveillance, required an improvement. For Designating Authorities, this guideline aims to describe medical devices scope expressions for Notified Bodies in a comparable and harmonized way.

2 Scope of the document

This guideline provides scope expressions, describing activities of NBs to demonstrate medical devices competence for their notification in the NANDO register. The expressions are defined per directives for DAs to achieve harmonized listings of NBs skills. In addition application for modifications can be submitted in a uniformed way to the European Commission responsible for maintenance the NANDO register.

This document is applicable to products according to Directive 93/42/EEC (MDD) concerning medical devices, Directive 90/385 (AIMDD) concerning active implantable medical devices and Directive 98/79/EC (IVDMDD) on *in vitro* diagnostic medical devices.

3 Concept for defining scope expressions

With this document a collection of existing relevant medical device information has been considered. This guideline takes reference to:

- NANDO register [1]
- The three main medical devices directives (MDD, AIMDD, IVDMDD)
- All modifying or implementing directives to the three main directives

- CEN Technical report CEN/TR 15133 : 2005 "Nomenclature – Collective terms and codes for groups of medical devices" [2]
- The Designating Authorities Handbook [3]

As explained in the Guide to Using [4], the NANDO register contains three levels of information per Directive. With one exception (89/106/EEC) this is handled in the same way for all NBs in all Directives, including the medical devices sector.

The list of the register with the description of the tasks performed for one NB and one Directive contains three columns, reflecting the three different levels. They are named "**Product families**", "**Procedures**" and "**Articles/Annexes**". Whereas for the level of the "Product families" neither a structure nor a specific wording exists, the information for the two other levels is well defined. This limits automatically any kind of harmonization to the Level of "Product families". Due to the fact that the NANDO structure should not be modified for individual Directives, particular attention was given to an understandable wording with an adjusted structure of scope expressions.

Scope expressions as they are recorded in the NANDO list have to correspond evidently with the competence of a NB. This competence shall be assessed, by taking reference to the DA Handbook [3].

At the end a clear statement with regard to the scope of the designation of a NB should be given. This can best be described with the listings in sections 3.1 to 3.6.

3.1 Medical devices, non-active, 93/42/EEC

CODE	MD SCOPE EXPRESSIONS, NON-ACTIVE MEDICAL DEVICES
MD 0100	**General non-active, non-implantable medical devices**
MD 0101	Non-active devices for anaesthesia, emergency and intensive care
MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
MD 0103	Non-active orthopaedic and rehabilitation devices
MD 0104	Non-active medical devices with measuring function
MD 0105	Non-active ophthalmologic devices
MD 0106	Non-active instruments
MD 0107	Contraceptive medical devices
MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
MD 0109	Non-active devices for *in vitro* fertilisation (IVF) and assisted reproductive technologies (ART)
MD 0200	**Non-active implants**
MD 0201	Non-active cardiovascular implants
MD 0202	Non-active orthopaedic implants
MD 0203	Non-active functional implants
MD 0204	Non-active soft tissue implants
MD 0300	**Devices for wound care**

MD 0301	Bandages and wound dressings
MD 0302	Suture material and clamps
MD 0303	Other medical devices for wound care
MD 0400	**Non-active dental devices and accessories**
MD 0401	Non-active dental equipment and instruments
MD 0402	Dental materials
MD 0403	Dental implants

3.2 Medical devices, active, 93/42/EEC

CODE	MD SCOPE EXPRESSIONS, ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES
MD 1100	**General active medical devices**
MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
MD 1102	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
MD 1103	Devices for stimulation or inhibition
MD 1104	Active surgical devices
MD 1105	Active ophthalmologic devices
MD 1106	Active dental devices
MD 1107	Active devices for disinfection and sterilisation
MD 1108	Active rehabilitation devices and active prostheses
MD 1109	Active devices for patient positioning and transport
MD 1110	Active devices for *in vitro* fertilisation (IVF) and assisted reproductive technologies (ART)
MD 1111	Software
MD 1200	**Devices for imaging**
MD 1201	Imaging devices utilising ionizing radiation
MD 1202	Imaging devices utilising non-ionizing radiation
MD 1300	**Monitoring devices**
MD 1301	Monitoring devices of non-vital physiological parameters
MD 1302	Monitoring devices of vital physiological parameters
MD 1400	**Devices for radiation therapy and thermo therapy**
MD 1401	Devices utilising ionizing radiation
MD 1402	Devices utilising non-ionizing radiation
MD 1403	Devices for hyperthermia / hypothermia

MD 1404	Devices for (extracorporal) shock-wave therapy (lithotripsy)

3.3 Active implantable medical devices, 90/385/EEC

CODE	AIMD SCOPE EXPRESSIONS
AIMD 0100	**General active implantable medical devices**
AIMD 0101	Active implantable medical devices for stimulation / inhibition
AIMD 0102	Active implantable medical devices delivering drugs or other substances
AIMD 0103	Active implantable medical devices substituting or replacing organ functions

3.4 In vitro diagnostic medical devices, 98/79/EC

CODE	IVD SCOPE EXPRESSIONS
IVD 0100	**List A** Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups
IVD 0101	AB0 system
IVD 0102	Rhesus (C, c, D, E, e)
IVD 0103	Anti-Kell
IVD 0200	**List A** Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of
IVD 0201	HIV infection (HIV 1 and 2)
IVD 0202	HTLV I and II
IVD 0203	Hepatitis B, C and D
IVD 0300	**List B** Reagents, reagent products and devices for self - diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating
IVD 0301	Anti-Duffy and anti-Kidd
IVD 0302	Irregular anti-erythrocytic antibodies
IVD 0303	Congenital infections: rubella, toxoplasmosis
IVD 0304	Hereditary disease: phenylketonuria
IVD 0305	Human infections: cytomegalovirus, chlamydia
IVD 0306	HLA tissue groups: DR, A, B
IVD 0307	Tumoral marker: PSA
IVD 0308	Risk of trisomy 21 (incl. software)

IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
IVD 0400	**Devices for self-testing**
IVD 0401	Clinical chemistry
IVD 0402	Haematology
IVD 0403	Immunology
IVD 0404	Molecular biology
IVD 0405	Pregnancy and ovulation
IVD 0406	Specimen receptacles

3.5 Specifics of medical devices and active medical devices, 93/42/EEC, 90/385/EEC

CODE	MD AND AIMD SCOPE EXPRESSIONS, ADDITIONS
MDS 7000	**MD / AIMD Specifics**
MDS 7001	Medical devices incorporating medicinal substances, according to Directive 2001/83/EC
MDS 7002	Medical devices utilising tissues of animal origin, including Directive 2003/32/EC
MDS 7003	Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC
MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)
MDS 7006	Medical devices in sterile condition
MDS 7007	Medical devices utilising micromechanics
MDS 7008	Medical devices utilising nanomaterials
MDS 7009	Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed

3.6 Specifics of in vitro diagnostic medical devices, 98/79/EC (IVDs)

CODE	IVD SCOPE EXPRESSIONS, ADDITIONS
MDS 7200	**IVD Specifics**
MDS 7206	IVDs in sterile condition
MDS 7207	IVDs utilising micromechanics
MDS 7208	IVDs utilising nanomaterials
MDS 7209	IVDs utilising biological active coating and/or material
MDS 7210	IVDs utilising material of human origin

Any change of or addition to the scope expressions is subject to NBOG endorsement.

The scope expressions consider different requirements of different directives, technologies, use of the devices and the risks associated with the devices. With such a demand there is strong requirement for a clear understanding of the content of each expression. To minimize definition discussions and to take in consideration the helpful development of the Technical Committee CEN/TC 257, this guidance uses the collective terms of the technical report CEN/TR 15133 [2] as a source of definition. The report has been prepared to specify terms associated to common technologies, similar manufacturing procedures, similar medical procedures, common materials and specific risk – associated considerations of medical devices. According to the report, these terms are appropriate for providing general groupings to meet particular requirements, such as to identify the range of skills and general technological abilities for which a NB has been approved.

Considering the intention of the mentioned report, the lists contain definitions by using or/and grouping collective terms. With such definitions, each list has a manageable quantity of scope expressions and the interested NANDO users have the chance to understand unambiguously the single expressions.

The technique of grouping collective terms to scope expressions can be explained with the following example:

- The MD 0204 scope expression “Non-active soft tissue implants” is defined by grouping collective terms together. The group contains terms, which could be brought in conjunction with the particular device.
- These collective terms can be for “soft tissue implants” (not exhaustive): CT:005, CT:091, CT:234, CT:088, CT: 165, CT:179, CT:143, CT:189, CT:185, CT:160, CT:140, CT:044, CT184, CT:208, CT:207, CT:212, CT:201, CT: 237.

Since the NANDO register distinguishes between directives, separate lists for each of the three directives (MDD, AIMD and IVDD) have been set up. The architecture of the lists differs between the directives.

The titles support the grouping and formation of structured scope expressions. This results in an improved overview.

To have a clear identification and allocation, each expression is assigned with a code. This code can be used as a reference for electronic transmission of data. The codes, ending with values to whole hundreds, are reserved for group titles, e.g. code “AIMD 0100” stands for the title “general active implantable medical devices”. The different expressions within the groups are sequentially numbered. But only the listed terms under each title, and not the titles themselves, are relevant expressions for demonstrating the NB’s competence. The prefixes take reference to the relevant directive and specialities, e.g. “MDS” for “specialities”.

The listings have been set up as a consensus result of NBOG. To ensure future consistency of the NANDO data entries, any change of or addition to the scope expressions is subject to NBOG endorsement.

4 Implementation

Designations of new NBs shall take into account the scope description as defined above. DAs forward this information to the European Commission responsible for maintaining the NANDO register as defined within the established electronic notification system.

The European Commission will implement the new structure in NANDO rapidly. The DAs shall change the scope of their existing NBs until 21 March 2010. Up to this time, both the new and old NANDO structure will be accessible in parallel.

References	Directive 93/42/EEC, Directive 90/385/EEC, Directive 98/79/EC
Sources	[1] NANDO (New Approach Notified and Designated Organisations) Information System
	[2] CEN/TR 15133 : 2005 "Nomenclature – Collective terms and codes for groups of medical devices"
	[3] NBOG Designating Authorities Handbook
	[4] NANDO Guide to Using Vers.1.0, 31 January 2008
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