IMPLEMENTATION OF MDD IN SLOVAK REPUBLIC

Andrea Suchánková, dipl. ing., dr Ivan Mikulecký, Prof. dr Janko Hodolič

***Abstrac**t: This research is part of Tempus ETIQUM Project which is financed by EU. This article covers the analyse of steps which were necessary for transposition and implementation of EU Directive on medical devices into the national legislation of the Slovak republic. It covers not only information about implementation but also mandatory periodic verification after placing the medical device with measuring function on the market as well.*
***Key words**: Education, EU Directives, Metrology, TEMPUS, Projec*

1. INTRODUCTION

This work is a part of results from international ETIQUM Tempus Project which has been focused on enhancement of continuing engineering education in Serbia. Duration of a project has been from Septmber 2007 till August 2009. One of the results of the project is a development of pilot courses for professionals from Serbian institutions and enterprises in quality standards and metrology. One of the project partner from EU member states is Slovak Institute of Metrology in Bratislava (SMU), Slovak republic. SMU together with experts from Mechanical Engineering Faculty of University of Belgrade and Faculty of Technical Sciences of University of Novi Sad has been responsible for development of a course relating to EU Directives on conformity assessment.

One of the EU Directive which related to conformity assessment of medical devices is an EU Directive No. Council Directive 93/42/EEC of 14 June 1993 (MDD), amended by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000, Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001, Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 and Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007.

This article presents way of implementation of MDD into Slovak national legislation.

The free movement of goods is the fundamental keystone of single market. The mechanisms which are suitable for achievement this particular goal are based on preventing market restrictions, mutual recognition and technical harmonization.

The Act No. 140/1998 Coll. on medicinal products and medical devices defines the medical device, which means a tool, instrument, optical device or any other article or material which is intended to be used for diagnostic, prevention and remedy, for alleviation or compensation for an injury or

handicapor control of conception. Also accessories intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device are considered as a medical device.

Medical devices are one of goods types which in the past created market barriers due to significant differences in legislation of individual EU member states. In the area of safety and health protection the nature of medical device has very often significant and serious meaning.

2. LEGISLATION

For the acceleration of elimination of market barriers there were approved three „new approach“ directives in the field of medical devices concerning:

- active implantable medical device – Council Directive 90/385/EEC of 20 June 1990 (AIMDD), amended by Council Directive 93/42/EEC of 14 June 1993, Council Directive 93/68/EEC of 22 July 1993, Regulation (EC) No 1882/2003 of EP and of the Council of 29 September 2003 and Directive 2007/47/EC of the EP and of the Counsil of 5 September 2007,
- medical devices – Council Directive 93/42/EEC

*This article is based on results from a project ETIQUM, Tempus JEP–41120-2006 „Education and training of institutions in quality management and metrology“.

1) Andrea Suchánková, dipl.ing, Slovak Institute of Metrology, Bratislava, Slovakia, mail: suchankova@smu.gov.sk
2) dr Ivan Mikulecký, Slovak Institute of Metrology, Braislava, Slovakia, mail: mikulecky@smu.gov.sk
3) Prof. dr Janko Hodolič, FTN, Trg Dositeja Obradoviča 6, Novi Sad, mail: hodolic@uns.ns.ac.yu

of 14 June 1993 (MDD), amended by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000, Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001, Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 and Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007

- in vitro diagnostic medical devices - Council Directive 98/79/EEC of 27 October 1998 (IVDD), amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003.

In the Slovak republic these directives were transposed into following Governmental Decrees of Slovak republic (NV SR):

- NV SR No. 570/2001 Coll., by which have been defined details on technical requirements and conformity assessment procedures of active implantable medical devices,
- NV SR No. 572/2001 Coll., by which have been defined details on technical requirements and conformity assessment procedures of medical devices,
- NV SR No. 569/2001 Coll., by which have been defined details on technical requirements and conformity assessment procedures of in vitro diagnostic medical devices.

During the transition period medical devices with measuring function might be placed on the market on the ground of conformity assessment or metrological control. After expiry of the transition period there was issued an amendment of the Order No. 210/2000 Coll. on measuring instruments and metrological control (the Order No. 669/2004 Coll.). From this amendment resulted that the placement on the market of medical devices with measuring function has been based on conformity assessment of this device. Subsequent verification relates to those devices, which are listed in the Annex No.1 of the amended order.

3. PLACEMENT ON THE MARKET

Medical devices can be placed on the market according to Article 10 of Act No.264/1999 Coll. on technical requirements of goods and conformity assessment in amendment only in the case if they fulfill technical requirements according to particular Governmental Decree (NV SR) and if medical devices after their right implementation, installation, maintenance and use are in compliance with intended purpose and do not jeopardize safety and health of patients, users and where appropriate other persons.

4. PARTICULARITY OF MEDICAL DEVICES WITH MEASURING FUNCTION

Medical devices with measuring function shall meet next-to general technical requirements also another following obligations.

According to NV SR No. 572/2001 Coll:

- medical devices must be designed and produced in such a way as to provide sufficiently accurate and reproducible measurement results within accuracy limits intended by manufacturer taking into account of intended purpose of device. The manufacturer must specify accuracy limit;
- measuring, control and display scale has to be designed in compliance with ergonomical principles in consideration of intended purpose of medical device;
- measuments done by medical devices with measuring function must be given in legal units.

According to NV SR No. 569/2001 Coll.:

- measuring, control and display scale (including colour change and other visial indicators) must be designed in line with ergonomical principles, taking account of the intended purpose of device;
- devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability accuracy and reproducibility of measurement within appropriate accuracy limits, taking into account the intended purposes of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer;
- when values are expressed numerically, they must be given in legal units.

5. ACHIEVEMENT OF TECHNICAL REQUIREMENTS

a) Achievement of requirements of harmonised European standards

The achievement of technical requirements is possible to be proved by meeting obligations imposed by harmonised European standards.

b) Achievement of directives requirements

In such a case that for particular medical device with measuring function no harmonized European standard exist, it is possible to achieve

technical requirements by proving direct fulfilment of requirements of NV SR No. 569/2001 Coll., No. 570/2001 Coll. and No.572/2001 Coll. where keywords are listed above in part „4. Particularity of medical devices with measuring function“ Example of such a medical device with measuring function is glucometer.

6. INTERPRETATION OF DIRECTIVES

Due to need of clarification of details and avoidance of ambiguous interpretation of directives European Commission issued guidelines for interpretation of Directives No.90/385/EEC and No.93/42/EEC. Guideline „Medical devices with a measuring function is called MEDDED 2.1/5 (June 1998). It appears from the fact that Annex VII, Article 5 of Directive No. 93/42/EEC requires for medical devices with measuring function Class I that manufacturer must also follow one of the conformity assessment procedures referred to in Annex IV, V or VI for the „aspects of manufacture concerned with the conformity of products wih the metrological requirements“.

It is therefore necessary to specify criteria for the existence of a „measuring function“ in a medical device.

The guideline contains criteria for medical devices with measuring function.

The following criteria, if fulfilled together, indicate that a device has a measuring function:

a) Medical device is intended by the manufacturer to measure:
   - quantitatively a physiological or anatomical parameter, or
   - a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body
b) The result of the measurement
   - is displayed in legal units or other acceptable units within the meaning of Directive 80/181/EEC or
   - is compared to at least one point of reference indicated in legal units or other acceptable units in compliance with the pre-mentioned directive.
c) The intended purpose implies accuraccy, claimed explicitly or implicitly, where a non-compliance with the implied accuracy could result in a significant adverse effect on the patient's health and safety.

Note 1: The expression „claimed implicitly“ covers cases where the user, on the basis of the designation of the medical device or of its accompanying documents, or on the basis of the common use is entitled to expect accuracy where the accuracy of the measurement has an impact on the diagnosis or therapy of the patient.

Note 2: Measuring activities during the manufacturing process including those for calibration purposes are not covered by this recommendation and do not imply a measuring function of the mnufactured device.

Examples for devices with a measuring function:

- device for measuring body temperature,
- pacifier which includes a temperature display including those with only a change of colour where criteria b is met,
- device for indicating that a body temperature is above or below a specified value,
- non-active non-invasive device for measuring blood pressure,
- non-active device for measuring intra-ocular pressure,
- device for measuring volume or pressure or flow of liquid or gases delivered to or removed from human body (included any container with a graduation scale or with a single point graduation where criteria c is met).

Examples for devices without a measuring function:

- patch for indicating trends of body temperature (where criteria b is not met),
- device for a delivery of liquid to the human body (e.g. medicine spoons, cups, droppers, without graduation or scale or dispay of measuring unit),
- device for displaying trends of physiological parameters (e.g. urine bags without graduation or scale, callipers for obesity),
- eye-test charts.

In addition to this fundamental interpretation guideline European Commission issued also a working document NA-mt-145-non automatic weighing instruments, where the objective is to define border between Directives No. 93/42/EEC concerning medical devices and No. 90/384/EEC concerning non-automatic weighing instruments.

The general definitions are following:

a) The non-automatic weighing instrument is an article, e.g. weighing instruments for infants;
b) The article is generally intended for determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment and the article is non-automatic weighing instrument. This instrument in the same time meets the obligations for definition of medical device, while the character of medical device can be second-rate in comparison with primary weighing function of the instrument, e.g. weighing instrument inbuilt into trolley intended for transport of patient or into hospital

bed;

c) The article can be used for different combined purposes, e.g. mass determination, measurement of blood pressure, EKG. Example: a combined device in which individual purposes are meet independently on each other;
d) The article is intended mainly for medical purposes and meet obligations for medical devices. The achievement of its fundamental medical function could be joined with mass determination function, which adds its original function, e.g. a computer tomograph, an incubator, a dialysis system.

In tha cases a), b), c) it can be applied Directive No. 90/384/EEC.
In the cases b) and c) in addition to Directive No. 90/384/EEC it can be applied also Directive No.93/42/EEC.
In the case d) it can be applied only Directive No. 93/42/EEC.

7. APPLICATION OF ANOTHER RELEVANT GOVERNMENTAL DECREES

If the medical device is an article with features which have to meet the obligations of another provisions, mainly Governmental Decrees of Slovak republic, e.g. concerning radiation protection, electromagtetic compatibility, etc., then affix of CE marking of conformity must comform to all relevant provisions.

8. NATIONAL LEGISLATION ON METROLOGICAL CONTROL AFTER PLACING OF DEVICE ON THE MARKET

The Annex No. 1 of the Order No. 210/2000 Coll. amended determines, that legally controlled measuring instruments are subject of mandatory periodic verification or initial verification after reparation.

9. SELECTION OF MODULS FOR CONFORMITY ASSESSMENT

The selection of particular conformity assessment modul is under responsibility of manifacturer decision, who includes the medical device into particular class according to NV SR No.572/2001 Coll. According to this provision the medical devices are grouped into 4 product classes (I, IIa, IIb and III), whereas usage of medical device of Class I constitutes the lowest risk and Class III the highest one. The demandingness of conformity assessment process depends on those classes as well.

Into Class I belongs following medical devices:

- non-invasive unless these, which can be connected to an active device in Class IIa or they are intended for channelling or storing blood, body liquids, organs or body tissues,
- non-invasive which come into contact of with injured skin, intended to be used as a mechanical barriere
- invasive intended for transient use other than surgically invasive devices and these which are not intend for connection to an active medical device
- surgically invasive, they are reusable surgical instruments
- all other active which are not mentioned in in other Classes.

There are also medical devices in Class I which are custom-made. The devices are assessed by manufacturer or authorized representative and authorized person controls them from metrological point of view only in the case if there is a medical device with measuring function. This type of medical devices do not carry CE mark.

Figure No. 1 showes possibility of conformity assessment procedures from the metrological point of view, which must be used by manufacturer for medical devices in Class I depending on intended function of the particular device.

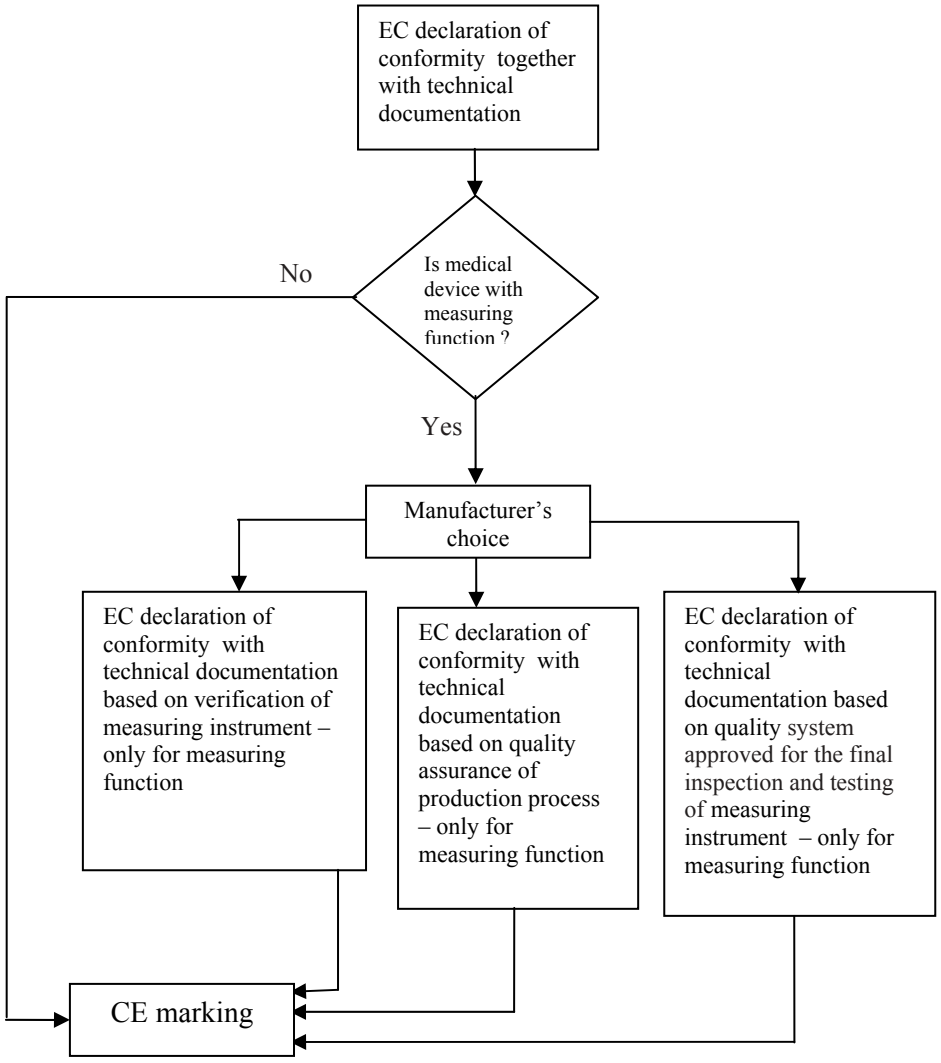

Figure No.1 Class I

The conformity assessment in the case of medical devices with measuring function in Class I, the conformity is declared by manufacturer (Annex 7 of NV SR No. 572/2001 Coll.) and consequently in the one of following ways selected by manufacturer:

1. by verification (Annex 4 of NV SR No. 572/2001 Coll.)
2. by system of production quality assurance (Annex 5 of NV SR No. 572/2001 Coll.)
3. by quality system approved for the final inspection and testing of product (Annex 6 of NV SR No. 572/2001 Coll.)

Application of the above mentioned modules and the intervention by the notified body is limited to only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

For the rest of medical devices which are falling in Class I without measuring function the declaration of conformity together with technical documentation is satisfactory.

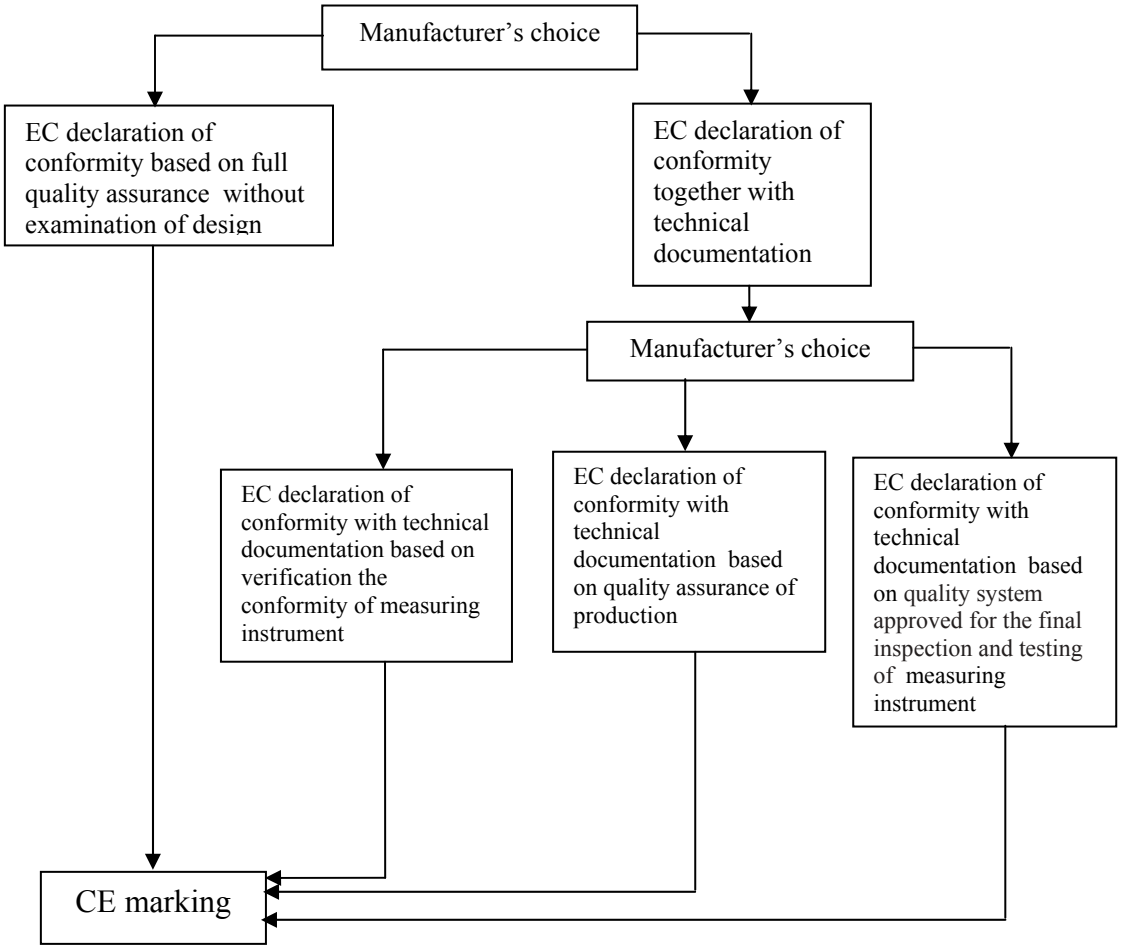

Figure No. 2 – Class IIa

The process of the conformity assessment of medical devices falling in Class IIa is performed by the EC declaration of conformity based on a full quality assurance system without examination of the design of the medical device (Annex 2 besides Section 4) or by the EC declaration of conformity with the technical documentation (Annex 7) after which follows the EC declaration of conformity with the technical documentation based on a verification of the measuring instrument (Annex 4) or by the EC declaration of conformity with the technical documentation based on a quality assurance of production process (Annex 5) or by the EC declaration of conformity with the technical documentation based on a quality system approved for the final inspection and testing of the measuring instrument (Annex 6) – Figure No.2.

The process of the conformity assessment of medical devices falling in Class IIb is performed by the EC declaration of conformity based on a full quality assurance system without examination of the design of the medical device (Annex 2 besides Section 4) or by the EC type-examination (Annex 3) after which follows the EC declaration of conformity where the manufacturer declares that the products concerned conform to the type described in the EC type-examination certificate based on a verification of the measuring instrument (Annex 4) or by the EC declaration of conformity where the manufacturer declares that the products concerned conform to the type described in the EC type-examination certificate based on a quality assurance system of production process (Annex 5) or by the EC declaration of conformity where the manufacturer declares that the products concerned conform to the type described in the EC type-examination certificate based on a quality system approved for the final inspection and testing of the measuring instrument (Annex 6) – Figure No. 3.

The process of conformity assessment of medical devices falling in Class III is performed by the EC declaration of conformity based on a full quality assurance system and the examination

of design of the medical device (Annex 2, Article 4 of NV SR č.572/2001 Coll.) or by the EC type-examination (Annex 3) after which follows the EC declaration of conformity where the manufacturer declares that the products concerned conform to the type described in the EC type-examination certificate based on a verification of measuring instrument (Annex 4). The verification is not required if the manufacturer ensures the application of the quality system approved for the manufacture of the products concerned (Annex 5) – Figure No.4.

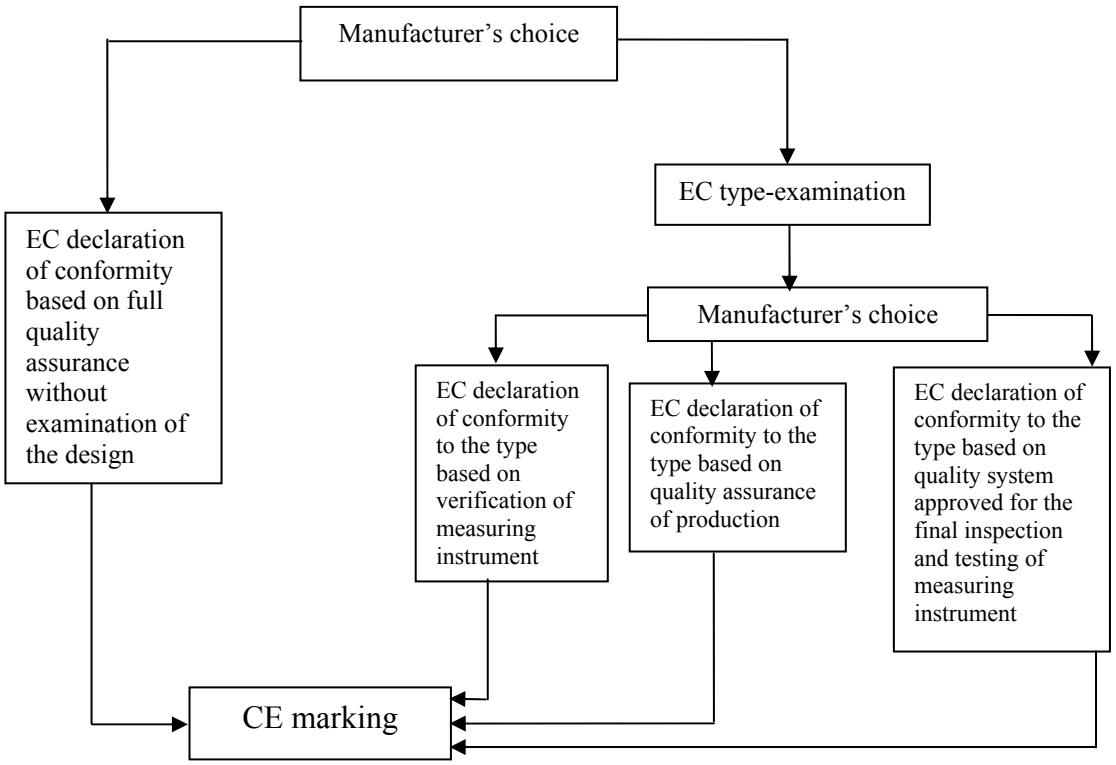

Figure No.3 – Class IIb

10. SURVEILLANCE BODIES

Surveillance of approved provisions implementation in the area of medical devices with measuring function has been carried out by Štátny ústav pre kontrolu liečiv (ŠUKL, State institute of drug control) and Slovenský metrologický inšpektorát (SMI, Slovak metrological inspectorate).

State institute of drug control (ŠUKL)

According to the Act on medicinal products and medical devices ŠUKL is responsible for ensuring surveillance of the quality, efficiency and safety of medicinal products for human use and medicinal products used in health care.

It has competences according to:

1. Act No. 140/1998 Coll. on medical products and medical devices,
2. Act No. 139/1998 Coll. on narcotics, psychotronic substances and compounds,
3. Act No. 331/2005 Coll. on state administration bodies related to drug precursors,
4. Act No. 264/1999 Coll. on technical requirements of goods and conformity assessment,
5. NV SR No. 572/2001 Coll., by which have been defined details on technical requirements and conformity assessment procedures of medical devices

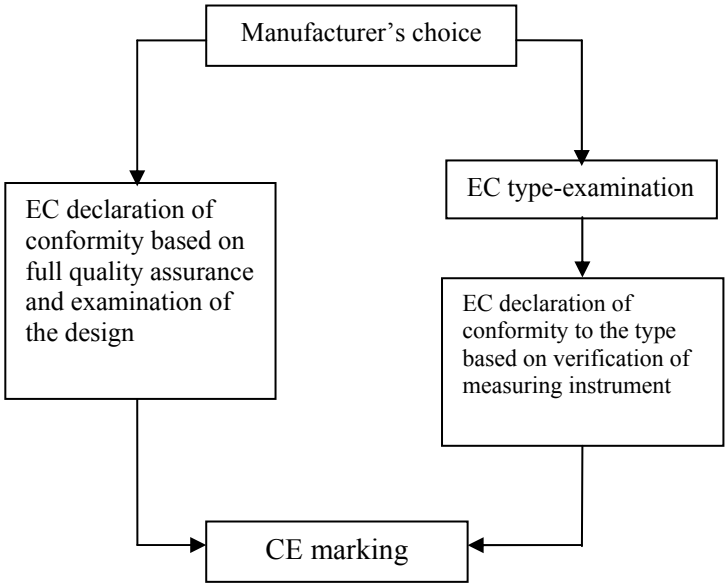

Figure No.4 – Class III and AIMD

Slovak metrological inspectorate (SMI)

According to the Act on metrology SMI is responsible for metrological surveillance and according to the Act on conformity assessment it is responsible for measuring instruments surveillance as well. It controls the observance of provisions of state administration bodies, manufacturers and importers of legally controlled measuring instruments, service organisations, users of legally controlled measuring instruments, packhouses and importers of customer packages with the aim to achieve the unification and accuracy of measurement in the Slovak republic, which has very substantive impact for customer protection.

Competences according to

- Act No. 142/2000 Coll. on metrology in the wording of the Act No. 431/2004 Coll. and relevant provisions
- Act No. 264/1999 Coll. on conformity assessment,
- Governmental Decree No. 399/1999 Coll. on non-automatic weighing instruments,
- Governmental Decree No. 572/2001 Coll. on medical devices,
- Governmental Decree No. 294/2004 Coll. on measuring instruments.

11. CONCLUSION

Directives EC, which affected medical devices with measuring function were transposed into Slovak legislation in the forms of Governmental Decrees. During the implementation process there was carried out the twinning project 2005/017-464.02.01 SK05/IB/IN/01/TL Reinforcement of Administrative Capacities as Regards Measuring Instruments (TWL) - Czech Republic which was very helpful in adopting Europan legislation.

12. REFERENCE

1. Nariadenie vlády Slovenskej republiky č. 572/2001 Z.z., ktorým sa ustanovujú podrobnosti o technických požiadavkách a postupoch posudzovania zhody zdravotníckych pomôcok. Zbierka zákonov SR č. 224/2000, p.5828
2. Zákon NR SR č. 264/1999 Z.z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov. Zbierka zákonov SR č. 113/1999, p.2097
3. Zákon NR SR č. 142/2000 Z.z. o metrológii v znení neskorších predpisov. Zbierka zákonov SR č. 61/2000, p.1678
4. Vyhláška ÚNMS č.210/2000 Z.z. o meradlách a metrologickej kontrole. Zbierka zákonov SR č. 91/2000, p.2550
5. Mikulecký, I. – Obdržálek, P.: Metrologická kontrola zdravotníckych pomôcok s meracou funkciou. Metrológia a skúšobníctvo, X, 2005, č.1, pp. 15 and 16.
6. Guidelines to the application of: the Council Directive 90/385/EEC on active implantable medical devices, the Council Directive 93/42/EEC on medical devices. Medical

devices with measuring function. European Commission, DG Enterprice. Medical devices: Guidance document MEDDEV 2. 1/5 June 1998.
7. Guidelines on medical devicesň. IVD Guidance: Borderline issues. A guide for manufacturers and notified bodies. European Commission, Enterprice Directorate – General, MEDDEV 2. 14/1 rev.1, January 2004
8. Guide to the Implementation of Directives based on New Approach and Global Approach. EOTC Info-Servis 1999, www.eotc.be
9. CE marking of medical devices. Instructions for use LNE/G-MED. Edition 2005
10. Mikulecký, I.: Podmienky uvádzania zdravotníckych pomôcok s meracou funkciou na trh podľa zákona NRSR č. 264/1999 Z.z.. Metrológia a skúšobníctvo, XIII, 2008, č.1, pp.19 - 26