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Conformity Assessment of Medical Devices according to Requirements of EU Directive

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Introduction

As far back when Lithuania has joined European Union appropriate product conformity assessment technical regulations were already confirmed, according to which the new approach directive requirements of European Economic Community (EC) were legitimated enabling the free movement of goods within the Community market. Accreditation (i.e. the verification of competence to perform objective and unbiased assessment) of conformity assessment institutions (testing and calibration laboratories, certification and control institutions) was taking place in parallel and is still in progress.

The certification center for electronic equipment "Sertika" was acknowledged as a notified body (NB) of conformity assessment of medical devices in Lithuania, which employs the specialists of highest qualification and which is the only institution of such type in the Baltic States of the former eastern block. European Commission Enterprise Directorate-General has announced that this company is provided with the identification number 1609.

Even though this company has not much of experience it observes that most of medical devices manufacturers hardly masters elaborate requirements of technical regulations and not always carry them out in an exact manner. The purpose of this paper is to reveal the main principles of conformity assessment and to provide generalized requirements of technical Regulation for medical devices [1] with the help of logical diagrams.

Actions of manufacturer before introducing the product to the market

Each manufacturer of medical devices, after ascertaining that his new product has to satisfy the requirements of the mentioned Regulation, has to perform the following actions before introducing the product to the market:

- to determine the class of medical device – 1, 2a, 2b or 3 (according to the rules provided in Regulation Annex 9);
- to determine, what medical devices directive [2] harmonized standards the product has to be in conformity with;
- to select the procedure of conformity assessment according to the determined class of the product which is described in the Regulation Chapter 7 and in Annexes 2, 3, 4, 5 or 6;
- to determine, if the product conformity assessment has to be carried out by NB;
- to ensure in the way of measurements and tests that the product conforms the essential requirements of Regulation Annex 1;
- closely work together with NB in order to accomplish all necessary measurements and tests or certifications, to permit the assessment of the quality management system and to ascertain that all required conformity assessment procedures are already carried out;
- to prepare and keep the Technical file of the product and other documents, indicated by the Regulation;
- properly fill and sign the Conformity declaration (according to requirements of Annex 7) or to prepare the statement about the devices of special purpose (according to requirement of Annex 8);
- to mark products, packaging and accompanying documentation using the CE logo.

The manufacturer is free to choose any NB in the territory of EC for the conformity assessment of medical device, provided that the accreditation area, i.e. the competence of the NB is proper regarding the type of the device. Main rule during the conformity assessment of medical device is that any medical device, considering its purpose, has to be safe and fully conform to the requirements of Regulation Annex 1.

Estimation of medical device class is performed according to the rules provided in Regulation Annex 9 considering the purpose of the device and classifying the devices as invasive and non-invasive, active therapeutical and active diagnostic. The proper class determination is very important, since the further selection of conformity

assessment procedure depends on that. The higher class of the device the more sophisticated conformity assessment procedure is provided by the Regulation.

The manufacturer has a possibility to select one of several provided conformity assessment procedures according to the course described by the Regulation, which would be most suitable to satisfy the Regulation requirements and the aims and possibilities of manufacturer. Primarily it is associated with the fact, whether the manufacturer has implemented in his company the quality management system according to ISO 13485 standard. The Regulation provides two ways for conformity assessment of medical devices (Fig.1): the first, when implemented quality management system is not mandatory to manufacturer (conformity assessment is possible for non-sterile and without measurement function medical devices of class 1 and for non-sterile products of higher classes); the second, when such system is mandatory (conformity assessment is possible for sterile products of classes 2a, 2b and 3). When manufacturer has the quality management system already implemented there is an opportunity to perform the product conformity assessment for any class of medical devices.

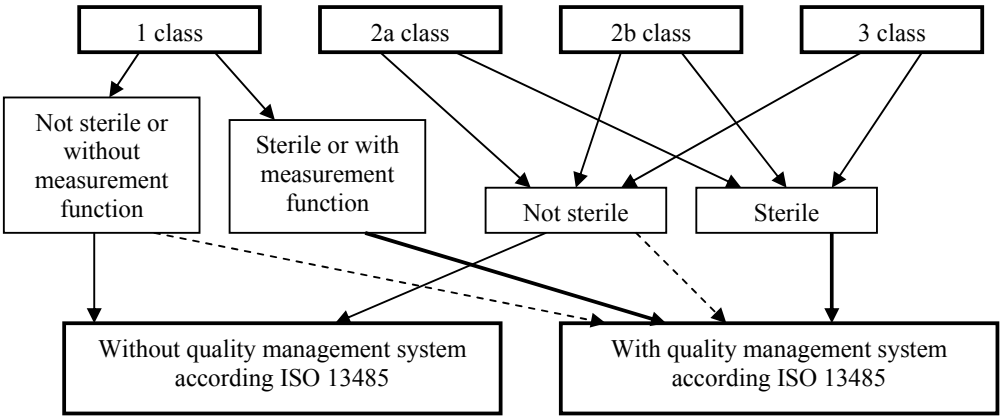

Fig. 1. Liaison between class of medical devices and manufacturer's quality management system

It is possible for manufacturer to dispense with the services of NB regarding the conformity assessment only in case non-sterile devices or devices without measurement function of class 1 are produced. In all the rest cases it is compulsory to apply to NB. Manufacturer delivers the sample product during submission of application to NB and prepares and presents documents listed in separate Regulation Annexes depending on the selected conformity assessment procedure.

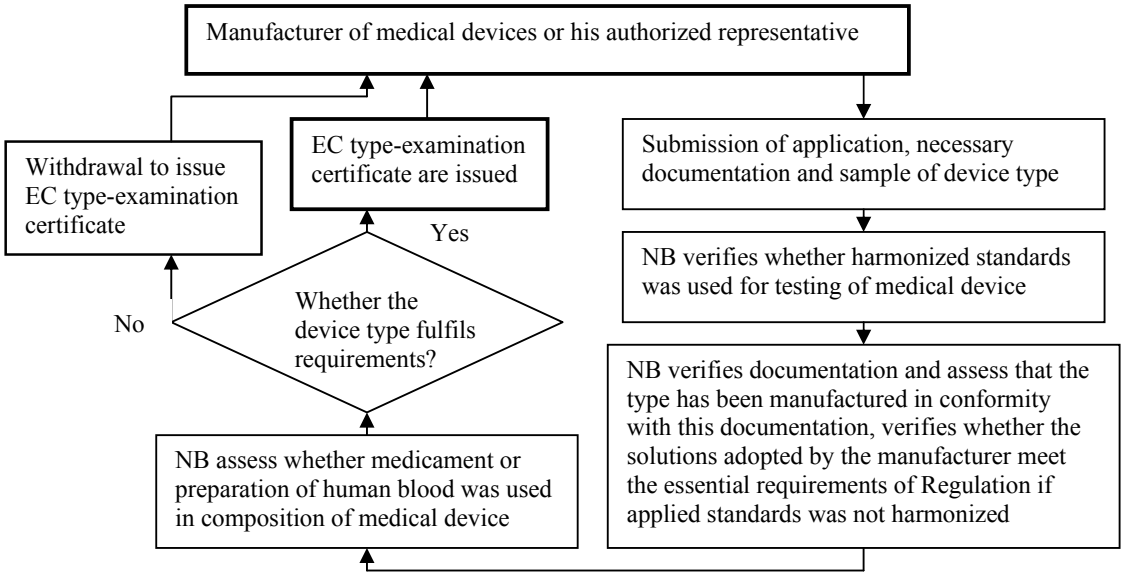

Fig. 2. Generalized conformity assessment schema according *EC type-examination* procedure

One important moment is that when medical devices of higher risk factor, i.e. class 2b or 3, are produced, manufacturer is given the opportunity to select between two types of conformity assessment procedures or to assess

the conformity to the Regulation requirements through *Full quality assurance system*, which is described in Regulation Annex 2, or to assess conformity through two stages: to perform *EC type examination* of the product in the NB, which is described in the Regulation Annex 3, and to receive *EC type certificate* of the device during the first stage, and to perform the further conformity assessment of product batches by the means of implemented quality management system, which is described in the Regulation Annexes 5 and 6 (*Production or product quality assurance)* for devices of class 2b, and described in Annex 5 (*Production quality assurance*) for devices of class 3, or

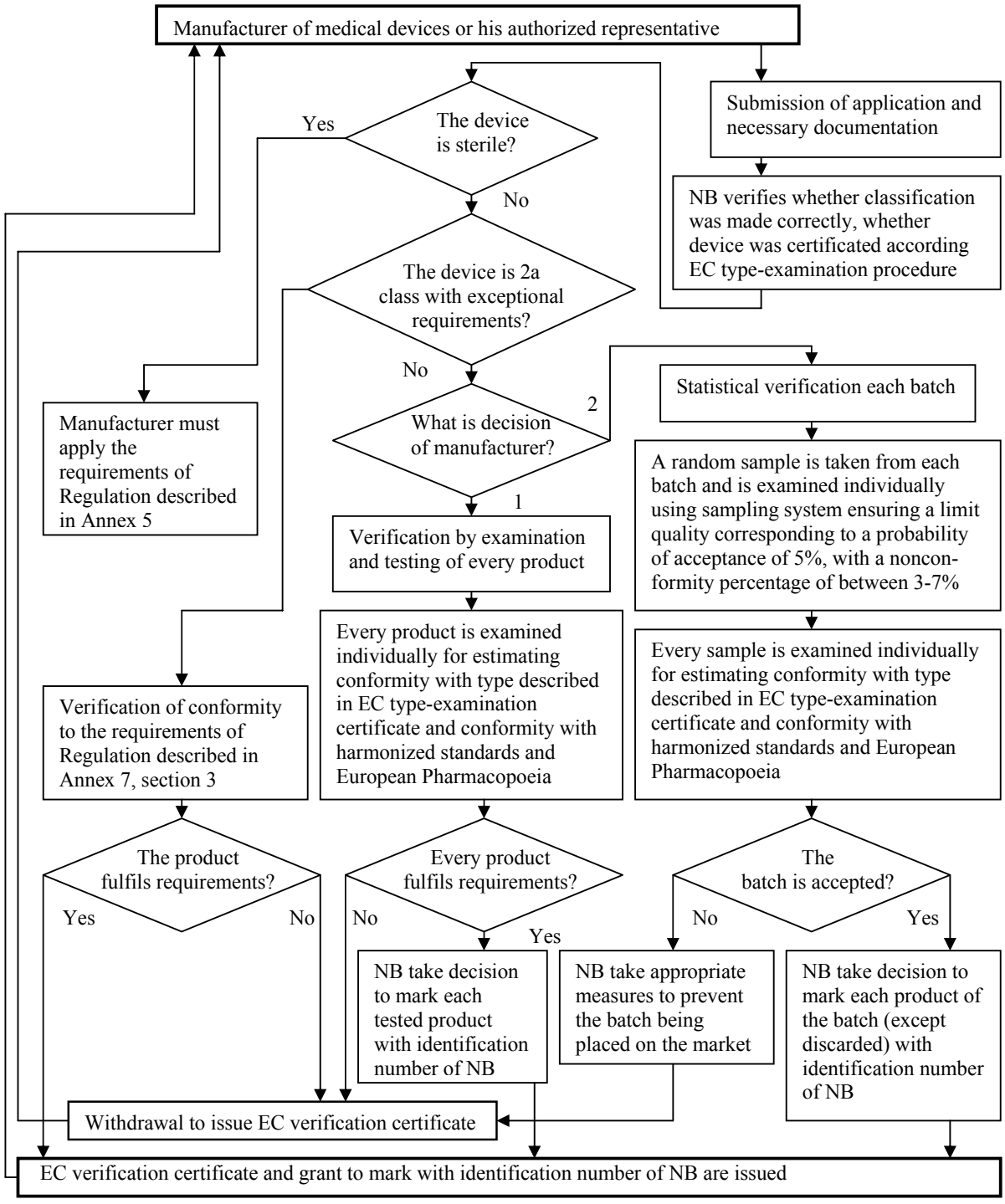

Fig. 3. Generalized conformity assessment schema according *EC verification* procedure

5 (*Production quality assurance*) for devices of class 3, or to certify the medical devices production batches in the NB (if products are non-sterile) according to the procedure, described in Regulation Annex 4 (*EC verification*).

Product conformity assessment through *Full quality assurance* is also intended in the Regulation for medical devices of class 2a, but there is no opportunity for them through *EC type examination*.

Since NB "Sertika" is accredited for conformity assessment of medical devices according to *EC type examination* procedure and according to *EC verification* procedure, for this reason generalized logical schemes are presented here illustrating how the conformity assessment of medical devices is performed according to the mentioned procedures (Fig.2 and Fig.3).

It should be noted that conformity assessment stage according to *EC type examination* procedure can be only applied for:

- medical device of class 2b (Regulation subsection 34.3);
- medical device of class 3 (Regulation subsection 34.4)

and the stage according to *EC verification* procedure can be applied in the following way:

- class 1 – when product is sterile or has the measurement function;
- class 2a – when product is manufactured according to requirements of technical documents (3 subsection of Annex 7) and according to the course defined in subsection 6 of Annex 7, and the NB performs appropriate inspections and tests to ascertain that product conforms to essential requirements of the Regulation (a part of subsection 4 of Annex 4) and documents indicated in subsection 3 of Annex 7;
- class 2b – when product is already certified according to *EC type examination* procedure;
- class 3 – when product is already certified according to *EC type examination* procedure.

A short overview of manufacturers of medical devices

Lithuania being a small state can not boast of having high number of manufacturers of medical devices. However the complexity scale of produced medical devices is sufficiently wide – from special-purpose devices manufactured according to individual orders to high complexity devices of ultrasonic diagnostics or laser-based medical devices. Regrettably the NB "Sertika" has not acquired competence to assess quality management systems of medical devices manufacturers yet, and this is the reason why it is still not able to offer its services in this area for manufacturers of medical devices of classes 2b and 3. Such companies like „Medelkom" Ltd., „Telemed" Ltd. were forced to apply to other NB of Europe regarding the introduction of quality management systems and at the same time regarding the conformity assessment of devices manufactured by them. „Lumen" Ltd., Laser Technology Center, IC „Dagda", IC „Medica", „Lemoks" Ltd. have applied to NB "Sertika" for production conformity assessment (without the quality management system evaluation), and „Viltechmeda" Ltd., „Taneta" Ltd., Medical Technologies company, JSC „Limeta", JSC „Puntukas" and many other smaller companies have applied to NB "Sertika" for fulfillment of safety tests according to appropriate standards of medical device directive.

Conclusions

Safety conformity assessment should be carried out for new medical devices before introducing them to the market according to requirements of directives or other medical norms accepted on the bases of directives in the national level. The manufacturers should correctly determine class of MD, to evaluate own aims and possibilities and make selection of particular conformity assessment procedure. After selection of procedure the manufacturers might correctly execute requirements of Regulation by applying conformity assessment logical schemes, part of them represented here.

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2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices // Official Journal. –12.7.1993. – No L169. – P. 1–46.

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Medical devices safety technical regulation requirements are shortly presented, commonly applied logical schemes of medical devices conformity assessment according to the third and fourth Annexes of Regulation are presented. Ill. 3, bibl. 2 (in English; summaries in English, Russian and Lithuanian).

С. Кашета. Оценка медицинских приборов на соответствие требованиям директивы ЕС // Электроника и электротехника. – Каунас: Технология, 2006. - № 4(68). – С. 91–94.

Коротко представлены требования технического регламента безопасности медицинских приборов, представлены часто используемые логические схемы оценки соответствия медицинских приборов по третьему и четвертому приложению регламента. Ил. 3, библ.2 (на английском языке; рефераты на английском, русском и литовском яз.).

S. Kašėta. Medicinos prietaisų atitikties įvertinimas pagal ES direktyvą // Elektronika ir elektrotechnika. – Kaunas: Technologija, 2006. – Nr. 4(68). – P. 91–94.

Glaustai išdėstyti medicinos prietaisų saugos techninio reglamento reikalavimai, pateiktos dažniausiai taikomos medicinos prietaisų atitikties įvertinimo loginės schemos pagal trečiąjį ir ketvirtąjį priedus. Il. 3, bibl. 2 (anglų kalba; santraukos anglų, rusų ir lietuvių k.).