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ENSURING EFFECTIVE MANAGEMENT OF MEDICAL DEVICES THROUGH SAFE USE OF MEDICAL DEVICES AND EVIDENCE-BASED MANAGEMENT

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Abstract. To ensure effective management of medical devices, it is imperative that medical devices must be safe and inoffensive, and their management must be based on evidence. Thus, to help enhance the safety of medical devices, a new mechanism for the periodic compliance assessment of medical devices has been developed. The mechanism involves the assessment of general safety, electrical safety and performance parameters in line with international best practice. At the same time, the effective management of medical devices requires data and information related to medical devices and their lifecycle events, which can be obtained through the medical device management information system. The establishment and implementation of efficient management of medical devices, involves strengthening the capacities of medical devices' management, in order to be able to respond to the current requirements of the health system, in such a way as to ensure the functionality of medical devices and the safe and efficient use of medical devices. Accordingly, the implementation of efficient management of medical devices is fundamental for providing qualitative, safe and efficient medical devices, which contributes to increasing the quality of medical services.

Keywords: *medical devices, information system, medical device management, periodic verification, security, performance, records, safety, efficiency.*

Rezumat. Pentru asigurarea unui management eficient a dispozitivelor medicale, este imperial necesar ca dispozitivele medicale să fie sigure și inofensive, iar gestionarea acestora să fie bazată pe evidență și dovezi. Astfel, pentru a contribui la sporirea siguranței dispozitivelor medicale, a fost elaborat un nou mecanism de evaluare periodică a conformității dispozitivelor medicale. Mecanismul presupune evaluarea parametrilor de securitate generală, de securitate electrică și parametrilor de performanță în conformitate cu cele mai bune practici internaționale. În același timp, pentru gestionarea eficientă a dispozitivelor medicale sunt necesare date și informații aferente dispozitivelor medicale și a evenimentelor ciclului de viață a acestora, care pot fi obținute prin intermediul sistemului informațional de management a dispozitivelor medicale. Stabilirea și implementarea unui management eficient al dispozitivelor medicale necesită fortificarea capacităților de gestionare a dispozitivelor medicale, pentru a putea răspunde cerințelor actuale ale sistemului de sănătate, astfel încât să se asigure funcționalitatea dispozitivelor medicale și

utilizarea sigură și eficientă a acestora. Drept rezultat, punerea în aplicare a unui management eficient al dispozitivelor medicale este fundamentală pentru utilizarea dispozitivelor medicale calitative, sigure și eficiente, ceea ce contribuie la creșterea calității serviciilor medicale.

Cuvinte-cheie: *dispozitive medicale, sistem informațional, management a dispozitivelor medicale, verificare periodică, securitate, performanță, evidență, siguranță, eficiență.*

1. Introduction

Currently, at the international and national level, it is certain that medical devices have become indispensable in the performance of medical acts.

At the same time, international experience shows us that the involvement of the necessary resources and the implementation of an efficient management of medical devices increase the performance of medical devices. Meanwhile, qualitative, efficient and safe medical devices, used at their maximum performance, contribute to increasing the quality and safety of medical services [1].

Accordingly, the streamlining of the medical device management system is an essential element in order to ensure the quality and safety of medical acts, and this must be in relation to the best international practices, as well as in accordance with the current requirements of the health system. The establishment of an efficient management of medical devices also involves strengthening management capacities in the field of medical devices by recording and ensuring the security and performance parameters of medical devices [2].

2. Medical device management information system

One of the basic conditions for efficient management of medical devices is the record of medical devices, in order to manage them correctly and efficiently. This involves the development and implementation of a national database, with the purpose of recording and managing data related to medical devices and their life cycle events, monitoring the traceability of medical devices, as well as planning the procurement and maintenance processes of medical devices.

Thus, in order to create the medical device management information system (MDMIS) in the field of medical devices, it was established that it must ensure:

- ✓ creating a secure information environment regarding medical devices in use;
- ✓ delivering truthful information in an operational manner;
- ✓ quick access to data and information regardless of location;
- ✓ continuous information of users and decision-makers in the management of medical devices;
- ✓ homogenization and totalization of information at local and national levels in the health system.

The MDMIS must be a tool designed to collect, store and report information about medical devices. And, the information must be provided to the users of the system, but also to the competent public authorities, such as the Ministry of Health, the Medicines and Medical Devices Agency (MMDA), etc., according to Figure 1.

According to Figure 1, Technical University of Moldova provides qualified personnel to medical institutions, which are users of the information system and are obliged to enter information about medical devices into the MDMIS. The Ministry of Health is the central public authority that develops and promotes policies in the field of medical devices.

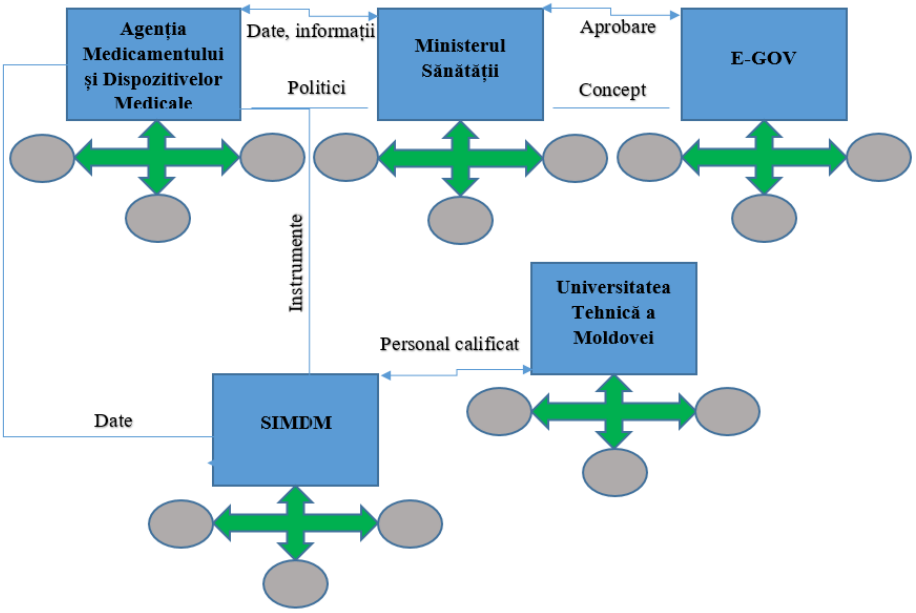

Figure 1. Organizational structure and correlation with MDMIS.

Based on the principles of the proper functioning of information systems, the Medical Devices Management Information System was developed [3,4]. According to the Order of the Ministry of Health No. 200 of 14.03.2017, its implementation became mandatory for all public medical institutions in the health system and will later be implemented in private medical institutions as well [5]. MDMIS was placed on the MMDA website (Figure 2).

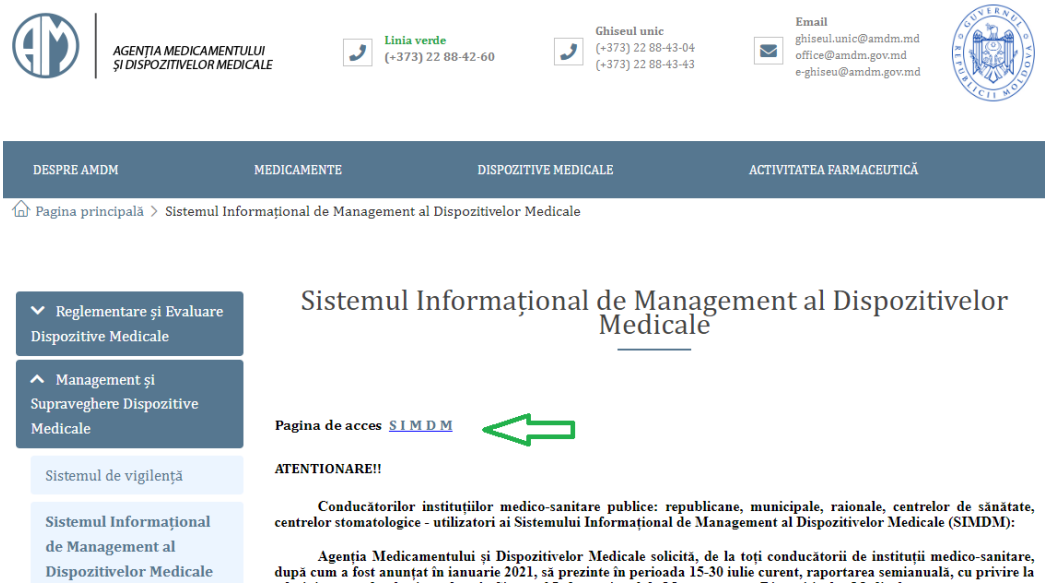

Figure 2. Access to MDMIS on the MMDA website.

MDMIS stores all information about medical devices, based on which reports can be generated for users of the information system, but also for the competent public authorities, in order to improve policies in the field of medical devices, and to facilitate decision-making within the management of medical devices. After receiving the login data from MMDA, the MDMIS page is accessed and the login data is entered, according to Figure 3 [6]. The next step consists of entering all the medical device data in the open window.

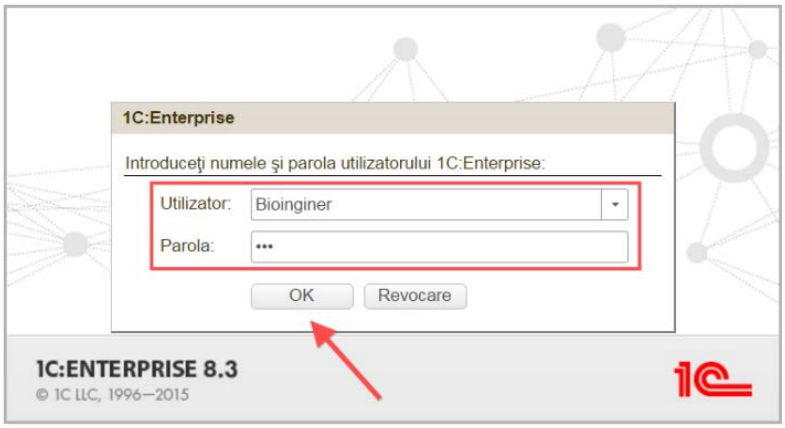

Figure 3. MDMIS login window.

In MDMIS, the following modules were provided, namely: the "Medical Devices" module; the "Consumables" module; the "Contacts" module; the "Employees" module; the "Maintenance" module; the "Periodic Check" module; the "Reports" module; the "Configuration" module; the "Tools" module; the "Vigilance" module; the "Security Subsystem" module.

All MDMIS users can access any of the 9 implemented functional modules, for example: medical device management, according to Figure 4.

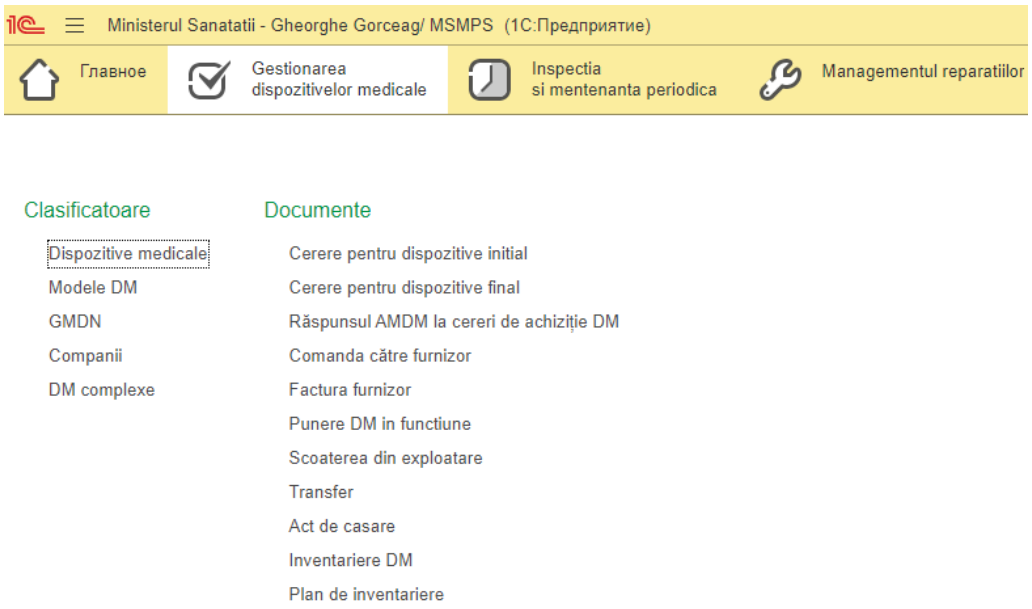

Figure 4. Medical Device Management module.

Accordingly, after entering information into the MDMIS about medical devices and related activities, data analysis reports or standard documents can be generated and provided based on predefined templates. This module can deliver the following types of reports:

- maintenance and testing report;
- engineer activity report;
- reporting of reaction time, repair time (downtime), type of defect;
- repair and activity report (medical department, bioengineers, repair time, response time, etc.);
- device report by (model, department, year of production, manufacturer, manager, price, serial number or inventory);
- report by years of receipt;

- report of hours of repairs, maintenance and inspection;
- report of available and used consumables and spare parts stock;
- report of consumables, used spare parts;
- incident reports;
- periodic verification, metrological reports;
- reports on medical devices by status (settled, intensively used, unused, defective);
- report by funding source.

With the development and implementation of MDMIS, by having a clear record of medical devices and data related to medical devices and their life cycle events, traceability of medical devices, data-driven decisions can be made regarding the replacement of certain medical devices, and the procurement and maintenance processes of medical devices can be planned. This constitutes an extremely important step in the efficient management of medical devices, and respectively, their efficient management [7].

Currently, MDMIS is implemented and can be used by all medical health facilities of the health system in the Republic of Moldova. At the same time, there is an opportunity to expand it also to private medical facilities.

3. Regulation of the mechanism for periodic verification of medical devices put into service and in use

At the same time, for efficient management and ensuring the use of safe, harmless and qualitative medical devices, it is imperative to ensure the compliance of the security, electrical safety and performance parameters of medical devices. The most appropriate and proper procedure by which the compliance of the security, electrical safety and performance parameters of medical devices can be confirmed is periodic verification.

In this regard, following the study and analysis of international practice with reference to the periodic verification of medical devices, in countries such as: Italy, France, the Netherlands, Romania, Japan, Switzerland, Germany, with the exception of the countries of the former USSR, for medical devices put into service and in use, periodic verifications are carried out through tests by laboratories/conformity assessment bodies (Figure 5) [8,9].

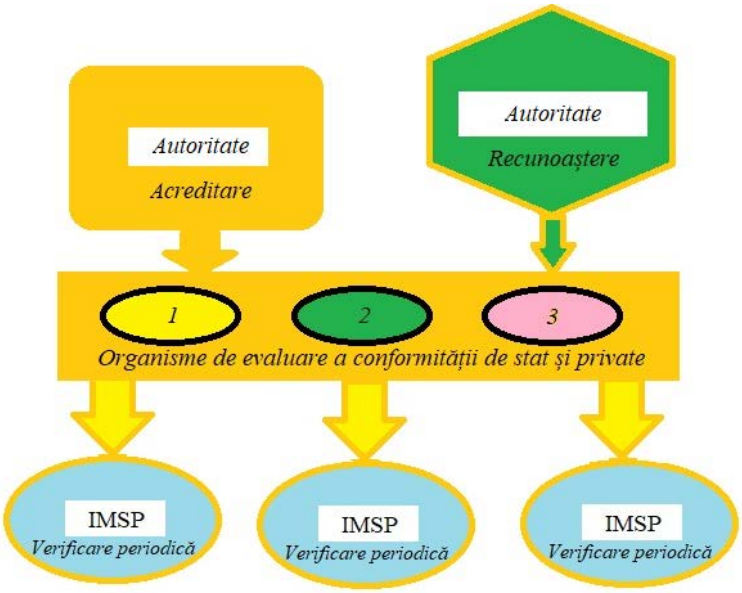

Figure 5. Model 1 of periodic verification practiced internationally.

At the same time, in some more developed countries, the same type of periodic verifications are practiced through tests, but these are carried out by bioengineers within medical institutions, who have their own testing equipment (Figure 6).

This implies that the medical institution must have the financial possibility to purchase and own the testing devices, including the instruments necessary for carrying out the periodic verification. At the same time, it is necessary to ensure the appropriate conditions for carrying out the periodic verifications, as well as the human resources (bioengineers, engineers) qualified and trained to be able to carry out the periodic verifications of the medical devices in the institution [10].

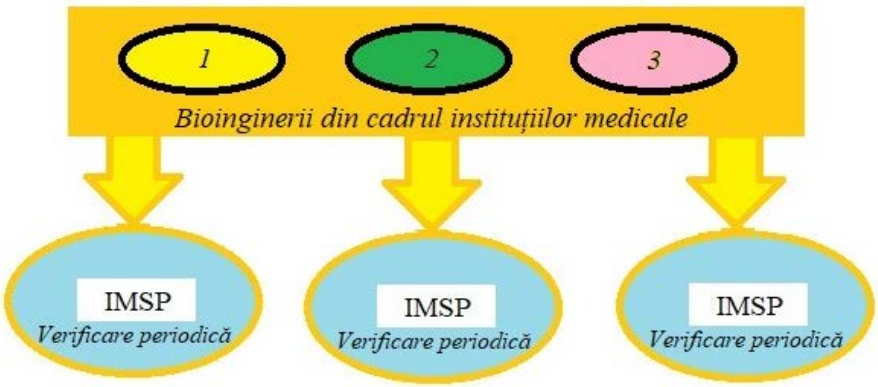

Figure 6. Model 2 of periodic verification practiced internationally.

At the national level, until 2017, medical devices that were qualified as measuring instruments were actually subject to metrological verifications that could not guarantee the conformity or the level of conformity of the safety parameters and, in particular, of the performance parameters. While, in the healthcare system, a wider variety of types of medical devices were exploited and used, important in terms of the intended purpose, with safety and performance parameters that required to be subject to periodic assessment through examination and laboratory tests. Respectively, on the one hand, the medical devices that were subject to metrological verification were insufficiently verified in terms of confirming the conformity of the safety and performance parameters. And, on the other hand, only a few types of medical devices, from the wide range of those used in the healthcare system, were subject to metrological verification (Figure 7).

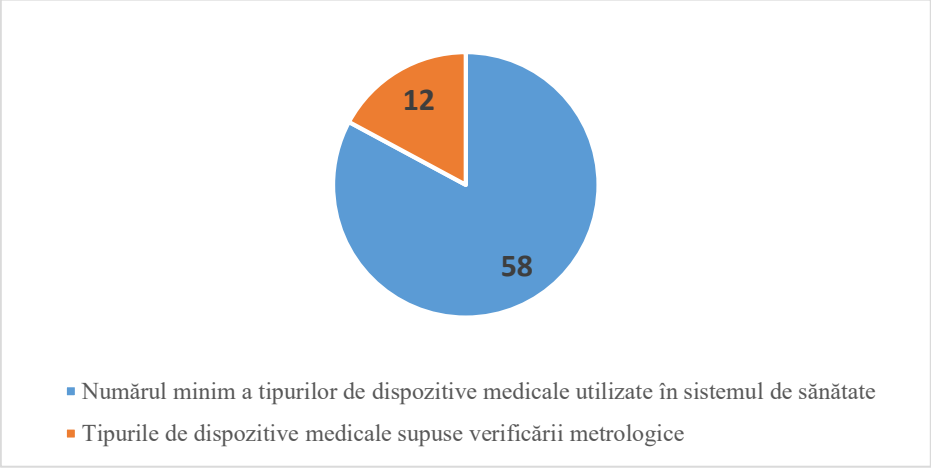

Figure 7. Ratio between medical devices subject to metrological verification and those used in the healthcare system that required periodic verification.

Accordingly, following the research and analysis carried out to develop the concept of periodic verification of medical devices put into service and in use in the healthcare system of the Republic of Moldova, we have identified several options or conceptual models for carrying out periodic verification, namely:

- by an accredited and recognized state laboratory;
- by bioengineers within medical institutions;
- by state and private conformity assessment bodies.

Considering the need for investments, as well as the allocation of human resources and appropriate spaces for carrying out periodic verification activities, conceptual model 3 (Figure 8) was identified as the most viable option, which involves carrying out periodic verifications by both state and private conformity assessment bodies [11-13]. In order for conformity assessment bodies to be admitted to carry out periodic verifications of medical devices put into service and in use, they must be accredited under the terms of Law no. 235/2011 on accreditation and conformity assessment activities, and subsequently recognized by the authority in the field, which is the Ministry of Health.

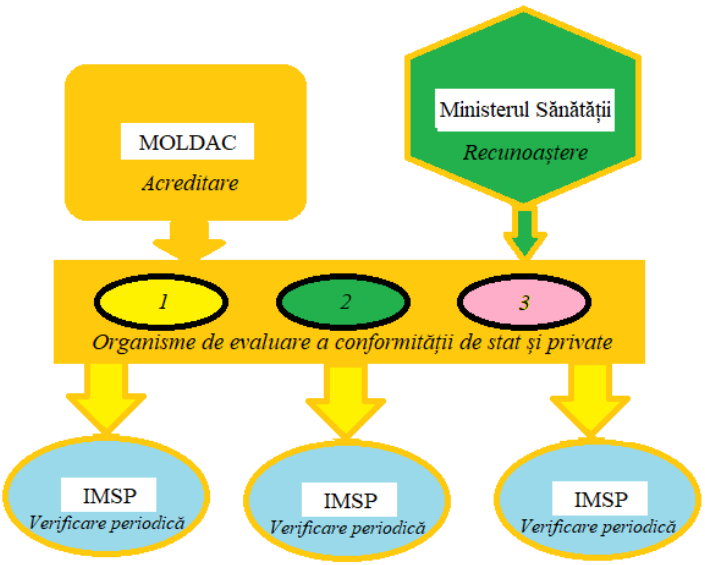

Figure 8. Conceptual model 3. Periodic verification of medical devices by state and private conformity assessment bodies.

The following step is the regulation of the mechanism for periodic verification of medical devices. Based on the provisions of Law No. 102 of June 9, 2017 on medical devices, we have developed and submitted for approval, the draft Government Decision for the approval of the Regulation on the periodic verification of medical devices put into service and in use, which was approved and became: Government Decision No. 966 of November 14, 2017, for the approval of the Regulation on the periodic verification of medical devices put into service and in use [14].

And, based on the approved Regulation, a draft order was developed regarding the specific procedures for periodic verification of medical devices (Figure 9), subsequently approved according to the Order of the Ministry of Health, Labor and Social Protection [15].

With the approval of the specific procedures for periodic verification of medical devices, we can say that the creation and implementation of a new system for periodic verification of medical devices has been achieved, which is an important step for the healthcare system of the Republic of Moldova, today the full regulatory framework is applicable to be able to carry out such periodic verifications of medical devices, at the national level.

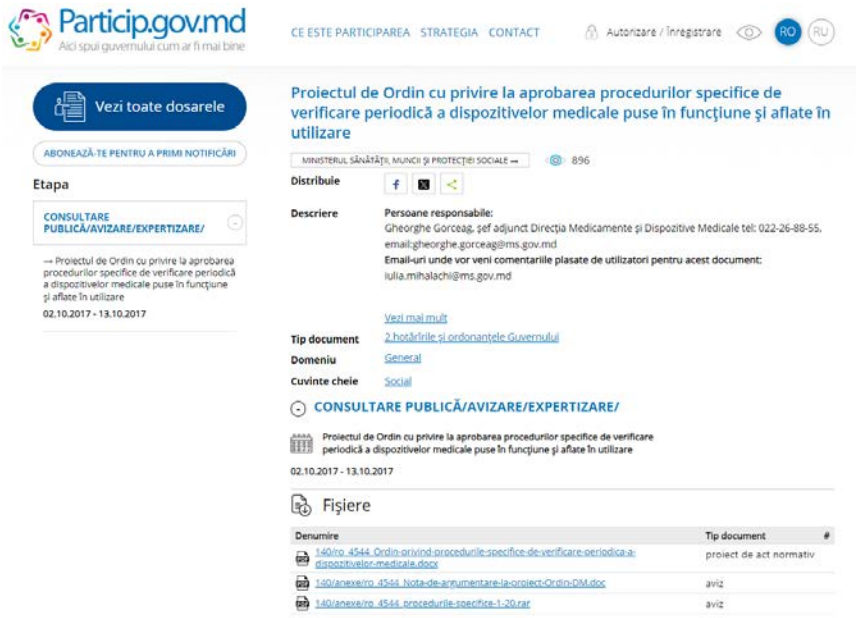

Figure 9. Draft order on specific verification procedures.

4. Discussions

MDMIS contains and provides data and information related to medical devices and their lifecycle events which is necessary for effective medical device management.

The information system has been developed following the Swiss model and is currently functional and implemented in all public health care institutions in the Republic of Moldova. It can also be extended to private medical facilities.

At the same time, the new mechanism for periodic conformity assessment of medical devices, which involves periodic assessment of general safety, electrical safety and performance parameters, is functional and implemented at national level. Respectively, all public health care institutions in the Republic of Moldova are obliged to ensure the periodic verification of medical devices.

Such types of periodic verification by laboratory tests are applied in the countries of the European Union, as well as in the USA, Japan, Australia, Ukraine, etc. In the ISC countries (countries of the ex-Soviet Union), metrological verification is still applied to medical devices, but not periodic verification by laboratory tests.

5. Conclusions

The Medical Device Management Information System is an extremely important step in the efficient management of medical devices, which together with the new system for periodic verification of medical devices contributes to the implementation of efficient management of medical devices. It allows a data-driven decisions making regarding the replacement of certain medical devices, or the procurement and maintenance of medical devices, as well as ensuring the health system with safe, high-quality and effective medical devices.

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