



Market authorization of medical products to world markets: the view of the Russian manufacturer

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The non-profit partnership “International association of developers, producers and users of medical technique” (**IAMT**) has been established and has been operating since 1991.

Goal:

Combining scientific and industrial efforts to solve issues related to the development of the medical industry.

Objectives:

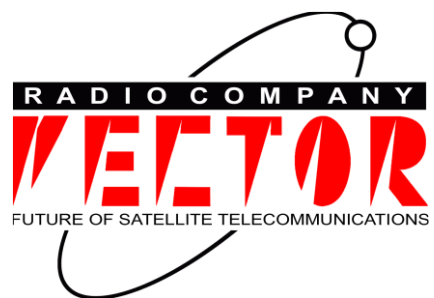
- Development and approval of the necessary medical industry legislation and regulatory framework;
- Expansion of the Russian and foreign medical market;
- Increasing the competitiveness of manufacturers in Russia and the countries of the EAEU, the CIS;
- Support for manufacturers in the existing market conditions;
- Interactions with government executive and legislative bodies in the field of medical device circulation.



- Cooperates with the Administration of the President of the Russian Federation, the State Duma, the Ministry of Health, the Ministry of Industry and Trade, the Ministry of Economic Development of the Russian Federation and other federal authorities in the preparation of National Health Programs, government and departmental programs for the development of the medical industry;
- Coordinates its activities with the Union of Associations and Enterprises of the Medical Industry of the Russian Federation, the Russian Union of Industrialists and Entrepreneurs and other organizations, including legislative and regulatory support for the medical industry;
- Actively works in conjunction with state organizations of the EEU, CIS and BRICS countries in solving problems of providing modern, competitive medical products and assists manufacturers in their promotion to the medical market;
- Actively promotes its products to countries in Asia, Africa, Latin America and Oceania through the mechanisms of bilateral Intergovernmental Commissions;
- It has brought together the most prominent developers, manufacturers of medical devices, service organizations, associations, more than 100 companies from Russia, Slovakia, Belarus, Bulgaria, Macedonia, and ensures the supply of medical products to healthcare institutions, including a number of high-tech products (more than 8,000 medical products);
- Provides organizational opportunities for the implementation of activities for the training and advanced training of technical and administrative personnel in the field of production, maintenance and operation of medical devices, the provision of consulting services.

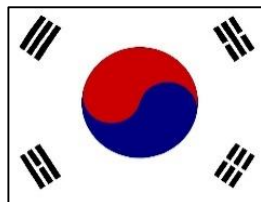
- Analysis of the prospects for the development of the Russian and international market of medical devices, in the light of transition to a digital economy and digital health care;
- Making recommendations for the medical industry development strategy based on continuous monitoring of the market of medical devices;
- Preparation of "road maps" to create new branches of the medical industry and ensure their maintenance;
- Increase in the share of medical devices that can function within the framework of the Unified State Health Information System and the National Telemedicine System;
- Study of the prospects for creating a unified system for monitoring the functioning of medical devices;
- Development of measures for import substitution of medical products in the Russian market;
- Creating associations of IAMT members to implement large export projects;
- Increase in the share of medical products in Russian non-resource export;
- Joint development with leading Russian and international financial institutions of financial and legal support schemes for export transactions of IAMT members;
- Creating favorable conditions for national exporters on world markets and in foreign countries.

IAMT core members with positive export experience



Cumulative export experience

- **IAMT** member companies export to the following countries and unions :



- Registration of medical devices is the quality of medical devices, the safety of medical devices, the effectiveness of medical devices in use;
- Development of high-tech, innovative, safe medical equipment production and promotion on the world market is possible only by harmonizing regulation of various countries.



Objectives of the Web Portal IAMT (www.medical-device.ru)



In the first quarter of 2015, the IAMT web portal and the Rosmedprom association web portal, which includes the **NP IAMT**, was put into operation.;

Objectives of the Web Portal :

- winning and strengthening the positions of IAMT members and the Rosmedprom Association on the national and international markets;
- support of work with partners, medical specialists and government agencies, in both Russia and other countries;
- ensuring the active support of the commercial activities of the members of the IAMT and the Association, drawing on the authority and experience of these professional associations.

The screenshot shows the homepage of the 'Medical Devices Information Portal' (Медицинские изделия Информационный портал). The header includes navigation links for 'INFO MEDICAL DEVICES RU' and 'ENGLISH'. The main title is 'МЕДИЦИНСКИЕ ИЗДЕЛИЯ ИНФОРМАЦИОННЫЙ ПОРТАЛ' with the English translation 'MEDICAL DEVICES, EQUIPMENT AND PRODUCT'. Below the header is a search bar with the text 'Введите слово для поиска' and a 'Найти' button. The main content area is divided into several sections:

- МЕДИЦИНСКИЕ ИЗДЕЛИЯ (КАТАЛОГ)**: A list of categories including 'ФИРМЫ УЧАСТНИКИ КАТАЛОГА', 'АССОЦИАЦИИ И ОРГАНИЗАЦИИ', 'НП "МОМТ"', 'АССОЦИАЦИЯ РОСМЕДПРОМ', 'ЭКСПЕРТНАЯ ПОДДЕРЖКА', 'ЗАКОНЫ И НОРМАТИВНЫЕ АКТЫ ПО ОБРАЩЕНИЮ МЕДИЦИНСКИХ ИЗДЕЛИЙ', 'КНИГИ И ПУБЛИКАЦИИ', and 'ТЕХНИЧЕСКОЕ ОБСЛУЖИВАНИЕ И РЕМОТ'.
- ЗАДАЧИ ПОРТАЛА:** A list of portal objectives such as 'информирование специалистов и потенциальных покупателей о медицинских изделиях, их характеристиках и услугах по поставке, обслуживанию и ремонту', 'информирование медицинских специалистов о новых приборах, технологиях лечения, методах публикации и формах обмена', 'публикация законодательной и нормативной документации, регулирующей обращение медицинских изделий, комментарии, обсуждения', and 'информирование о сотрудничестве между НП МОМТ, Ассоциацией Росмедпром и министерствами и другими государственными структурами, а также медицинскими Ассоциациями и зарубежными Объединениями производителей медицинских изделий'.
- ПОСЛЕДНИЕ НОВОСТИ**: A section for news, featuring an article about 'Здравоохранение 2014 - 24-я российская неделя здравоохранения' (Healthcare 2014 - 24th Russian Week of Healthcare) held from December 8-12, 2014, in Moscow. It also mentions a meeting of the NP 'MOMT' board of directors on October 17, 2014.

Analysis of the availability of markets for medical devices for manufacturers



■ Appealing markets

Market selection criteria

Key markets	Scope	Fast growth	Low barriers
• Latin America	✓	✓	✓
• Western Europe	✓		
• Eastern Europe (except CIS)	✓		
• Middle East and North Africa		✓	✓
• Japan	✓		
• South Korea	✓	✓	✓
• China	✓		
• Southeast Asian countries		✓	
• Sub-Saharan Africa		✓	
• CIS		✓	

- **The problem of double registration.** The company must go through the registration procedure 2 times: according to the national standard and international standard. This problem makes it necessary to train employees according to different standards and delays the implementation of projects.
- **Various registration schemes.** Lack of consolidated information on registration conditions for medical devices in different countries.
- **The problem of uniform standards.** In order to integrate local producers into the world market and increase export potential, the harmonization of Russian standards with world standards is required.

IAMT offers to associations and organizations
working in the field of medical device circulation
to unite efforts

We are looking forward to cooperation.
Thank you!

