Use of improved Standards from the Russian industry perspective

Moscow, March 2019

IMEDA
International Medical Device Manufacturers Association

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Boston Scientific
Advancing science for life
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SIEMENS Healthineers
HARTMANN
Dräger
TERUMO
stryker
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GE Healthcare
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BIO-RAD
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FUJIFILM
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ООО «БЕЛЛА Восток»
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MÖLNLYCKE HEALTH CARE
BECKMAN COULTER
We're better togeth
BIOMÉRIEUX
PIONEERING DIAGNOSTICS
Arthrex
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Cepheid
A better way.
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INTERSURGICAL
FRESENIUS KABI
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AT THE HEART OF MEDICAL TECHNOLOGY
Baxter
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straumann
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About IMEDA

IMEDA (International Medical Device Manufacturers Association) – A non-profit organization uniting international manufacturers of medical equipment, products, and consumables on the Russian market founded in 2005

IMEDA – common voice of international manufacturers of Medical Devices in **RUSSIA**

IMEDA's Mission

Improving the efficiency of the Health Care System by introducing new technologies and providing the Russian population with modern, high-quality and affordable medical devices

Today the Association unites more than 50 leading international companies operating in the field of high-tech medicine in

RUSSIA

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The International Medical Device Regulators Forum (IMDRF) – established in February 2011 in order to harmonize regulatory requirements for the treatment of medical devices at the international level.

IMDRF Management Committee – the Supreme body of the Forum consisting of official representatives of 10 regulatory bodies of the participating countries.

The current members are:

Australia
Brazil
Canada
China
Europe
Japan
Russia (November, 2013)
Singapore
South Korea, and
the United States of America.

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International Medical Device Manufacturers Association

IMDRF topics cover all aspects related to the regulation of MDs:

1. Documents submission
2. Registration
3. Labeling
4. **Standards**
5. Clinical Evaluation
6. Quality Management System
7. Medical Software
8. ….. etc.

Standards for MDs in RUSSIA

2002 – Federal Law «On technical regulation» №184

2015 – Federal Law «On standardization» №162

Possibility to use international standards for regulatory compliance + national GOSTs

2022 – Launch of the common MDs market for **EAEU countries**

Common List of standards for conformity assessment approved (needs to be extended/updated in cooperation with the industry)

MDs – today subject to double conformity assessment procedure in Russia
(registration + declaration of conformity)

Recommendation: to unite all requirements into one procedure

Standards for MDs in RUSSIA

Industry expertise + Regulatory Authority participation/work on international level + Synchronized approach to approve internationally recognized standards = KEY for safe Medical Devices come to the market globally

Importance of HARMONIZATION for Standards globally

Unique opportunity for Russia to use the best achievements/state of the art products of the global MedTech industry as well as the most advanced regulatory practices to be implemented on the Russian soil while being a part of IMDRF

This will for sure result into **PROGRESS** for the local market

Importance of internationally recognized Standards for MDs in RUSSIA

- ✓ Powerful instrument. Internationally recognized standards help facilitate regulatory 'approximation' globally
- ✓ It ensures industry bring high-quality products to different markets faster
- ✓ Acknowledge of international standards in Russia (in accordance with Federal Law "On Standartization"). *Adding of a duly certified translation of an international standard to the national Fund of standards. Then applicant can conduct tests*
- ✓ Limited state budget resources. Few standards update financed from the state budget
- ✓ Necessity of getting industry involved into standards development/update process
- ✓Balanced approach in using standards for regulatory/market surveillance purposes. *Possibility to conform to the latest version of international Standard directly*

Importance of internationally recognized Standards for MDs in RUSSIA

✓ Use of updated international standards brings progress to national markets and makes industry meet higher requirements

✓ Role of industrial Association in development/updating of standards (national/EAEU level)

✓ Only joint efforts of “Regulator – Standards developer – Industry” can lead to the desired result

THE VOICE OF INTERNATIONAL MEDICAL DEVICE INDUSTRY IN RUSSIA

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