Use of improved Standards from the Russian industry perspective

Moscow, March 2019

IMEDA
International Medical Device Manufacturers Association

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Abbott
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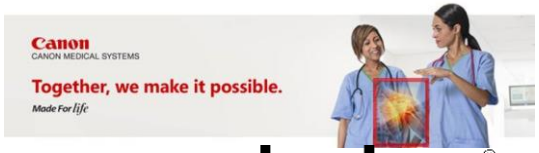
ZIMMER BIOMET
Your progress. Our promise.
PHILIPS
sysmex
VALEANT
FRESENIUS MEDICAL CARE
URSAPHARM
BARD
BD
KAVO Kerr
OLYMPUS
Your Vision. Our Future
Boston Scientific
Advancing science for life™
Medtronic
3M
Roche


SIEMENS Healthineers
HARTMANN
Dräger
TERUMO
stryker
smith&nephew
Roche
MERZ
GE Healthcare
ASCENSIA Diabetes Care
BAYER
SCA Care of Life
BIO-RAD
MERIT MEDICAL
FUJIFILM
BIOTRONIK
Edwards
ООО «БЕЛЛА Восток»
seni
matopat
MÖLNLYCKE HEALTH CARE
BECKMAN COULTER
We're better togeth
BIOMÉRIEUX
PIONEERING DIAGNOSTICS
Arthrex
OMRON
Cepheid
A better way.
Alcon
A Novartis Division
INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
FRESENIUS KABI
SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY
Baxter
Ortho Clinical Diagnostics
Allergan
straumann
ConvaTec
Alvogen

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

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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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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