

INTERNATIONAL CERTIFICATION  
OF MEDICAL PRODUCTS: A VIEW  
OF A RUSSIAN MANUFACTURER



# International Association of Designers, Manufacturers and Users of Medical Equipment



Established in 1991

**63 leading producers** of Russia, Belorussia, Bulgaria, Macedonia  
more than **8000** types of medical devices produced

**Goal:** Consolidation of scientific and industrial efforts to support medical industry



## JSC «PA «UOMP» is a Major Russian Manufacturer of Medical Equipment



**JSC «Ural Optical and Mechanical Plant named after E.S.Yalamov»**

**Parent company:** Holding «Shvabe» of Rostec State Corporation

**Location:** Russia, Ekaterinburg  
**Employees:** 2 586

**Quality management system**

ISO 9001-2015,  
 GOST PB 0015-002-2012,  
 EN 9100:2016

**Products are certified with**

EN ISO 13485-2016,  
 93/42/EEC

**Russian Government Quality Award - 2018**



**10 sales affiliates** in Russia

**3 overseas subsidiaries.**

**Shvabe – Zurich GmbH** sales affiliate, an OBL-manufacturer (Own Brand Labelling).

The equipment supplied to **47 countries** worldwide

## Overview of the Russian Medical Industry

- Developing market - **CAGR rate 5,5% for 2013-2025**
- Ongoing national projects and federal programs of health care support
- **€ 23 bln** - total amount of Government funding by a National Project “Healthcare”
- Government support of international industrial cooperation and preferences to localized products subject to correspond the criteria of a national product
- Craving for larger exports



## International Industrial Cooperation

**X** Instead of net imports

Joint development & production  
of medical devices in Russia

# Positive Practice of Harmonization with EU Requirements

## Russian-based clinical tests verification abroad

Technical and clinical evaluation held in Russia are valid abroad (excl. CIS countries) when Russian company applies for CE/FDA Certificates



## No need of equipment supply and repeating tests



### JSC "PA "UOMP" Treaton Electronic Systems Positive experience

- Indonesia
- Sri Lanka
- Vietnam
- Philippines
- Pakistan
- Qatar
- Turkey
- Ethiopia



## Suggestions for further harmonization

### Common regulatory area within the EAEU (Russia, Belorussia, Kazakhstan, Armenia, Kyrgyzstan area)

- Unified standards and requirements of QM (e.g. Unified QMS)
- Common EAEU system of technical files verification for medical devices (Mutual recognition of the clinical evaluation and laboratory tests)



### Mutual verification of the EAEU and European QM certificates



**WE ARE OPEN TO COOPERATION**

**THANK YOU!**

