

Medical device manufacturing in Russian Federation and harmonization with international practices



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Quality management system for medical devices

IMDRF Recommendations

ISO 13485:2003

MDSAP

Requirements for implementation, maintenance and assessment of quality management system for medical devices (Approved by decision № 106 of Eurasian Economic Commission's Council dated November 10, 2017)

(are obligatory for application after 2021 (partially allowed for use after 2025))

GOST ISO 13485-2017 «Medical devices. Quality management systems. Requirements for regulatory purposes»

Requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development or provision of associated activities (e.g. technical support).

Assessment of quality management system for medical devices is carried out for processes:

- 1) **design and development, if they are included in the quality management system of the medical device manufacturer;**
- 2) **production and service provision;**
- 3) **customer-related processes;**
- 4) **corrective and preventive action;**
- 5) **records management processes.**

If the manufacturer has implemented a quality management system for medical devices in accordance with the requirements of standards equivalent to the international standard ISO 13485, the inspection is limited by verification of requirements related to processes No. **1-3.**

Control of materials that are used in production of implantable medical devices

The list of medical materials (at the development stage)

information about class of material, its brand name, type, size of half-finished products, that can be made from it, and characteristics of half-finished products in accordance with operational documentation

information about manufacturers of medical materials

information about manufacturers of implantable medical devices produced with the help of additive technologies

Examples of localization of medical devices in Russian Federation

«Johnson & Johnson» localized production of glucose meters and test strips of the worldwide brand OneTouch at the Russian plant «Pharmstandard»
(Ufa)

NGO Scanner produce ultrasound scanners in cooperation with South Korean company Samsung Medison
(Kaluga)

The joint venture between «MEDICAL TECHNOLOGIES Ltd» and «General Electric Healthcare» launched the production of computed tomography equipment and ultrasound equipment
(Moscow region)

«Phillips» in cooperation with «Amico» started production of ultrasound systems and computed tomography equipment
(Moscow region)

* According to analytical companies, production output of medical devices in Russian Federation in 2018 (producer prices) is estimated at 62.3 billion rubles (8.3% compared to the same period in 2017). The market size of medical devices in 2018 amounted to 282 billion rubles (+10.46% by 2017). The share of local medical devices increased 22.8% compared to 21.0% in 2017.

Thank you for your attention!