

## Sky Medical designs and establishes ISO Class 8, 250m<sup>2</sup> cleanroom facility for Clever Medical in Almaty, Kazakhstan



*“I want to revolutionize the market for sterile medical devices and products by replacing imports with autonomous, locally-produced sterile products. Sky Medical proved to be the ideal partner to achieve this, because they have the relevant experience, are agile and responsive, and have sufficient presence to provide optimal solutions.”*

Askar Ayteliev, CEO, Clever Medical

### The Challenge

To date, medical products and devices have been imported to Kazakhstan. However, high transportation and import costs coupled with inflexible medical products that often tend to be unsuitable for the Central Asian market led to a demand for local production. Clever Medical was established to meet this demand and sought to create a facility for the in-house production of sterile medical devices and products which would comply with the stringent international standards and regulations for quality and safety.

### The Solution

Clever Medical engaged Sky Medical to plan and establish a medical device cleanroom production facility and infrastructure. The company was selected because of its ability to deliver a turnkey project - from planning to realization and validation - of a cleanroom and the related infrastructure using reliable and certified suppliers and materials; its knowhow in establishing a Quality Management System (QMS); and its extensive ERP support and ongoing consultant services.





*“Sky Medical offered fast responses and direct access to a very professional team. They understood our goals and delivered an unsurpassed level of quality. We look forward to continuing working with them as we move forward with our plans.”*

Askar Ayteliev, CEO, Clever Medical



## The Result

**Production Facility:** Planning, establishment and validation of a facility and the necessary infrastructure for the production of sterile medical products and devices in Kazakhstan.

**Quality Management System:** Establishment of a QMS for the facility, including guidelines for implementation and operation, and the creation of Quality Assurance, Quality Control and sterilization validation procedures.

**Ongoing Consultant Services:** Provision of support in the establishment and operation of a facility ERP solution and guiding Clever Medical throughout the ISO approval process.

**Facility for a Range of Products:** Establishment of a facility suitable for the local production of a range of medical products and devices, all of which are currently imported. Examples include:

- Fast deployment angiographic & cardiac surgery kits
- Medical diagnostic catheters
- Invasive blood pressure monitoring systems
- Medical drainage tubes.

## About Sky Medical

Sky Medical is a contract manufacturer of medical devices, offering full-scale services from initial runs of prototypes to large volume production, including product assembly, packaging, sterilization, storage and logistics. Producing components and devices that will be used to save or enhance a patient’s life, the company is committed to the highest quality standards. Sky Medical services are based on extensive experience and knowhow of more than 20 years in the medical device manufacturing and distribution market, enabling the company to be agile and responsive to OEM partner goals and needs.

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