

QUALITY POLICY

Attachment no. 3 to KJ
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Valid from: 20.04.2019

Issue: 1

PRODUCT QUALITY AND HEALTH SAFETY POLICY

KINGMED's mission is to produce handmade orthopedic insoles that will meet the expectations of demanding customers and to create and develop a market for our products at home and abroad. The overall goal is to ensure customer satisfaction by meeting its needs and achieving strategic goals by ensuring professionalism of services and security of offered health products. To complete our mission, we are constantly expanding our range of products.

To meet customer requirements and legal regulations, the company implements and improves the Integrated Quality Management System in accordance with the requirements of ISO 13485: 2016 and ISO 9001: 2015.

The quality and medical safety goals of the product are:

- · ensuring high quality and health safety of manufactured inserts
- constant supervision and care for storage and distribution conditions of manufactured inserts
- meeting safety and quality requirements in accordance with applicable law

The goals set should be achieved through:

- Continuous improvement of the product quality 1% of complaints
- Analysis of customer needs and expectations 99% of satisfied customers
- Constant monitoring of the market in order to collect information and the ability to react quickly in case of unfavorable information about products - contact with the company is always possible by phone or email
- Identifying and complying with legal requirements applicable in the organization and relating to products - supervision of legal requirements (verification every 6 months)



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Risk analysis of ongoing processes

- Careful selection of suppliers meticulous assessment of suppliers and contracts with suppliers
- Continuous development and improvement of employees' professional qualifications - employee training and assessment of training effectiveness (knowledge tests)
- Implementation of post-production activities related to medical devices product supervision
- Once a year, a review of the usefulness of the adopted Quality Policy and the objectives set, as well as the entire Quality Management System.

On behalf of myself and the staff, I declare the implementation of the established quality policy objectives along with improvement and development of the Integrated Quality Management System in accordance with the requirements of ISO 9001: 2015 and ISO 13485: 2016, as well as compliance with legal requirements and principles defined by the company. Kingmed declares to maintain the Integrated Quality Management System and asserts continuous development and assurance of medical safety of our products

20.04.2019

(date and signature of the owner)

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