

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
172476-2015-AQ-LTU-FINAS

Initial certification date:
30 January 2015

Valid:
31 January 2024 – 30 January 2027

This is to certify that the management system of
UAB Ortho Baltic
Taikos pr. 131A, LT-51124, Kaunas, Lithuania
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:

Design, adjustment for patient needs, production, distribution and service of standard and custom-made assistive orthopaedic devices. Design and distribution of standard and custom-made orthopaedic, cranio-maxillofacial and dental implants, dental prosthesis group products and single-use custom-made surgical instruments (guides). Development, maintenance and user support of web-based platforms, adapted for medical purposes. Ambulatory diagnostic and treatment services. Research and development of orthopaedic, cranio-maxillofacial and dental medical devices.

Place and date:
Espoo, 29 January 2024

For the issuing office:
DNV - Business Assurance
Keilaranta 1, 02150 Espoo, Finland



Kimmo Haarala
Management Representative

Appendix to Certificate

UAB Ortho Baltic

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
UAB Ortho Baltic	Taikos pr. 131A, LT-51124, Kaunas, Lithuania	Design, adjustment for patient needs, production, distribution and service of standard and custom-made assistive orthopaedic devices. Design and distribution of standard and custom-made orthopaedic, cranio-maxillofacial and dental implants, dental prosthesis group products and single-use custom-made surgical instruments (guides). Development, maintenance and user support of web-based platforms, adapted for medical purposes. Ambulatory diagnostic and treatment services. Research and development of orthopaedic, cranio-maxillofacial and dental medical devices.
UAB SMART FACTORY	Taikos pr. 131A, LT-51124, Kaunas, Lithuania	Production and distribution of standard and custom-made assistive orthopaedic devices. Production and distribution of standard and custom-made orthopaedic, cranio-maxillofacial and dental implants, dental prosthesis group products and single-use custom-made surgical instruments (guides). Contract manufacturing of customer designed medical devices or their components.