

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
256415-2018-AQ-FIN-FINAS

Initial certification date:  
05 June 1997

Valid:  
01 March 2024 – 28 February 2027

This is to certify that the management system of

**Biohit Oyj**

Laippatie 1, FI-00880 Helsinki, Finland

has been found to conform to the Quality Management System standard:

**ISO 13485:2016**

This certificate is valid for the following scope:

**Design/development, manufacture, marketing, and sales/distribution of in vitro diagnostic medical devices, including near-patient tests, and acetaldehyde binding medical devices used in the diagnosis and/or management of gastrointestinal diseases, risk of cancer, and different health statuses/disorders.**

**Design/development, manufacture, marketing, and sales/distribution of biological raw materials for the research and diagnostic markets.**

Place and date:  
Espoo, 29 February 2024

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



**Kimmo Haarala**  
Management Representative