

MANAGEMENT SYSTEM CERTIFICATE

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

Initial certification date:
05 June 1997

Valid:
01 March 2021 – 29 February 2024

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, 04 February 2021



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

Kimmo Haarala
Management Representative