

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
256415-2018-AQ-FIN-FINAS

Initial certification date:
05 June 1997

Valid:
29 August 2018 - 28 February 2021

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 acetaldehyde binding medical devices and in vitro diagnostic medical devices used in the diagnosis of risk of gastric cancer, immune status, disease/health status, autoimmune status, gastric disorders, including near patient in vitro diagnostic devices.

Place and date:
Espoo, 29 August 2018



For the issuing office:
DNV GL Business Assurance Finland Oy Ab

A handwritten signature in blue ink, appearing to read "Kimmo Haarala", is written over a horizontal line.

Kimmo Haarala
Management Representative