BIOHIT HealthCare

Innovating for Health

CE

Digitally signed by Bunic Gheorghe
Date: 2019.11.19 23:21:13 CET
Reason: MoldSign Signature
Location: Moldova

EC Declaration of Conformity

I, the undersigned, hereby declare that the Product(s)

Helicobacter pylori IgG Elisa, Cat. No. 601 040.02
Gastrin-17 Elisa, Cat. No. 601 035
Pepsinogen I Elisa, Cat. No. 601 010.01
Pepsinogen II Elisa, Cat. No. 601 020.02
Lactose Intolerance, quick test, Cat. No.s 602 010 (25 tests) and 602 012 (10 tests)
Lactase CONTROL+, Cat. No. 602 018
***Helicobacter pylori*, quick test, Cat. No. 602 015**
BIOHIT *Helicobacter pylori* UFT300, quick test
Cat. No.s 602 005, 602 005PLA (5 tests), 602 019, 602 019PLA (50 tests)
and 602 021 (100 tests)
***Helicobacter pylori* CONTROL+, Cat. No. 602 017**
BIOHIT Celiac quick test, Cat. No. 602 070
BIOHIT ColonView, Cat. No. 602 250.02
BIOHIT Calprotectin ELISA, Cat. No. 602 260
BIOHIT Extraction Tubes, Cat. No. 602 270
BIOHIT Active B12 (Holotranscobalamin), Cat. No. 602 290
Gastrin-17 Stabilizer, Cat. No.s 601 050 (1 x 5,5 ml) and 601 051 (5 x 5,5 ml)
GastroPanel: Pepsinogen I, Pepsinogen II, *H. pylori*, Gastrin-17 Elisa, Cat No. 601 300

Conform to the applicable provisions of EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices. Category: Other/General devices.

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (excluding point 6) of the Directive.

Standards applied:

ISO 9001:2008, ISO 13485:2003

Certificate No. 111839-2012-AQ-FIN-FINAS issued by DNV on 09 February 2015

ISO 14001 Certificate No. 111840-2012-AE-FIN-FINAS issued by DNV on 09 February 2015

ISO 13485:2003 Certificate No. CERT-0075001 issued by QMI SAI Global on 08 March 2015

Signed: _____ Date: 24th June, 2015

Name: **Semi Korpela**

Title: **President & CEO**

Company: **Biohit Oyj, Laippatie 1, 00880 Helsinki, Finland**

DNV·GL

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

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

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

Kimmo Haarala
Management Representative