



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**