BIOHIT HealthCare

Innovating for Health

CE

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EC Declaration of Conformity

I, the undersigned, hereby declare that the devices

Lactose Intolerance quick test; REF 602010 (25 tests) and REF 602012 (10 tests)

BIOHIT Lactase Control; REF 602018

***Helicobacter pylori* quick test; REF 602015**

BIOHIT *Helicobacter pylori* UFT300; REFs 602005PLA (5 tests), 602019, 602019PLA (50 tests) and 602021 (100 tests)

BIOHIT *Helicobacter pylori* Control; REF 602017

BIOHIT Celiac quick test; REF 602070

BIOHIT ColonView quick test; REF 602250.02

BIOHIT ColonView QT Control; REF 602390

conform to the applicable provisions of EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices (IVDD). 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 IVDD.

This declaration of conformity is issued under the sole responsibility of Biohit Oyj.

Place and date of issue: Helsinki, 25th May 2022

Signed by the Biohit Oyj designated representative:

Name: Jussi Hahtela

Title: CFO

BIOHIT OYJ * LAIPPATIE 1 00880 HELSINKI FINLAND * BIOHIT OYJ

Name of manufacturer: Biohit Oyj

Address: Laippatie 1, FI-00880 Helsinki, Finland

Actor ID: FI-MF-000014642

Appendices: 1. Standards applied, in full or in part, during the design and manufacture of the devices