Public declaration regarding the manufacture and use of in-house devices by health institutions

Name of health institution: Jilab Oy

Address: Biokatu 6, Finn-Medi 1 building, 3rd floor, 33520 Tampere, Finland.

Jilab Oy declares that the devices described in the accompanying table are only manufactured and used in Jilab Oy and do meet the applicable general safety and performance requirements (GSPR) of Annex 1 laid out in the *in vitro* diagnostic medical devices Regulation (EU 2017/746).

Date and location: 29 April 2024, Tampere, Finland

Name, function and signature of responsible person(s): Jorma Isola, Chief Executive Officer

Table of in-house devices:

Device identification (e.g. name, description, reference number)	Devic e type (IVD/ MD)	Intended purpose
Quantitative histomorphometry of celiac disease duodenal biopsies, including: • Hematoxylin & Eosin (H&E) staining • Villus Height – Crypt Depth analysis • CD3-IEL IHC staining and analysis • CD8-IEL IHC staining and analysis • Ki-67-IEL IHC staining and analysis • TCR-gammadelta-IEL IHC staining and analysis • MUM1 IHC staining and analysis • Q-MARSH classification • Marsh-Oberhuber classification	IVD	The intended use of these tests is to assess villus height (Vh), crypt depth (Cd), inflammation and proliferation seen in intestinal mucosa of celiac disease patients. These tests are for professional use and are single-site tests performed at Jilab Oy, Finland.