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

Name of health institution: Suomen Terveystalo Oy

Address: Jaakonkatu 3 A, 00100 Helsinki

Suomen Terveystalo Oy declares that the devices described in the accompanying table are only manufactured and used in Suomen Terveystalo Oy and do meet the applicable general safety and performance requirements (GSPR) of the medical devices Regulation (EU 2017/745). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Date and location: 22.1.2024 Helsinki

Name, function and signature of responsible person(s):

Jani Hopia, Quality Manager

Table of in-house devices:

Device identification (e.g. name, description, reference number)	Device type (IVD/ MD)	Risk class of the device	Intended purpose	Applicable GSPR fully met? (Y/N)	Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR/MDR)
Terveyskysely, version 1.0.0	MD	2a	Sante is intended to be used for indicating health- and wellbeing-related findings that predict potential problems with work	Y	

			ability, based on data provided by the lay users. Professionals may use the analysis results as background information for diagnosis and treatment decisions. Lay users may use the analysis results for personal decision making to improve personal wellbeing. Sante shall neither be used for self-diagnosing medical conditions nor for evaluating acute symptoms or the need for medical attention due to acute symptoms. Sante does not make diagnostics or treatment decisions.		