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: 27.10.2026 Tampere

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



Annika Rökman, SaMD 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)**
Terveystalo Medical Calculators (TMC) version 1.X.Y	MD	I	Terveystalo Medical Calculators (TMC) is a software application intended to perform predefined, clinically established medical calculations based on patient-specific data	Y	

			entered by healthcare professionals or patients and/or obtained from connected information systems. The software generates calculated values, scores, and predefined result categories based on validated medical formulas, scoring systems, and established calculation methods. The calculated results may be viewed by healthcare professionals and patients for information, documentation, and communication purposes within healthcare processes. The software provides standardized calculation results and, where applicable, predefined result categories determined solely by the thresholds, cut-offs, or classification criteria of the underlying calculation method. TMC does not generate patient-specific clinical conclusions beyond these predefined outputs. Clinical interpretation of the results and any subsequent clinical decisions remain the responsibility of a qualified healthcare professional.		