

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: 23.5.2025 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)
Work Disability Risk Analyzer 1.X.Y	MD	1	WD Risk Analyzer is intended to be used for indicating findings that predict potential	Y	

			<p>problems with work ability, based on data collected from different sources, including electronic medical records and questionnaires from which it creates a notification for a registered occupational healthcare professional. Based on the notification, the professional may invite the customer for an occupational health check-up. WD Risk Analyzer does not provide information which is used to take decisions with diagnosis or therapeutic purposes.</p>		
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