EU Quality Management System Certificate FI22/871876

The quality management system of

DigiFinland Oy

Toinen linja 14
FI-00530 Helsinki
Finland

SRN: FI-MF-000002451
has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745

on Medical Devices, Annex IX chapters I, III and TDA in section 4

For the following

Clinical decision support software

Devices covered, risk classification, standards and common specifications followed as well as applicable test and audit reports referred to, are listed in the Attachment 1 of this certificate

This certificate is valid from 31 May 2023 until 15 May 2025
and remains valid subject to satisfactory surveillance.
Issue 4. Certified since 16 May 2022
This certification is based on decision: FI23/08115P0

Authorised by

Seppo Vahasalo, NB Manager
SGS Fimko Ltd., Notified Body 0598

FINAS
Finnish Accreditation Service
S009 (EN ISO/IEC 17021-1)

SGS Fimko Ltd
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Business ID 0978538-5 Member of the SGS Group (SGS SA)

Attachment 1 to SGS Fimko Ltd. Quality Management System certificate FI22/871876, Issue 4

Manufacturer	DigiFinland Oy	**SRN** FI-MF-000002451
Address	Toinen linja 14 Helsinki FI-00530 Finland	
Other addresses covered by the certificate	Location	Activity at the location
	N/A	N/A
Activity and Device Category	MDR (EU) 2017/745 Annex IX chapters I, III and TDA of section 4, Clinical decision support software	
EU Authorised Representative	N/A	

Device or Device Group, EMDN Code	Risk Class	Identification Details and Intended Purposes
Clinical decision support software V92 Medical device software – not included in other classes	IIa	Omaolo version: 5.2 Module 1: Omaolo Oirearviot - Hampaiden tai suun alueen oire tai vamma -oirearvio - Hengitystietulehduksen oirearvio - Kurkkukivun oirearvio - Yskän oirearvio - Korvakivun oirearvio - Närästyksen oirearvio - Olkapään kivun oirearvio - Peräaukon oireen oirearvio - Polven oireiden oirearvio - Ripulin oirearvio - Alaselkäkivun oirearvio - Päänsäryn oirearvio - Silmätulehduksen oirearvio - Virtsatietulehduksen oirearvio - Seksitautien oirearvio - Yleinen oirekysely - Koronavirustaudin oirearvio Module 2: Omaolo Hyvinvointitarkastus - Terveystarkastus oirearvio Module 3: Omaolo Pitkäaikaissairauksien seuranta - Verenpaineen seuranta

The certification is based on the software version indicated here. Non-significant updates to the software need to be implicated in the software version identifier.

The certification decision is based on the following:

Report	Identification	Date
Notification of change review report	FIMEDc297111-DigiFinlandOy-FPMDREG1008-MDR-NoC-Omaolo-Ver-5.2-2023-04-24-Approved-2023-04-26	2023-04-26

Applied Standards / Common specifications
EN ISO 13845:2016, EN ISO 13845:2016/A11:2021 IEC 62304:2006+AMD 1:2015 EN ISO 14971:2019 IEC 62366-1:2015

Conditions for or limitations to the validity of the certificate
PMCF investigation to be planned and conducted for Omaolo 5.0 or later Module 1 variant "Hampaiden tai suun alueen oire tai vamma -oirearvio"

Preceding certificate and its attachment 1
FI22/871876 issue 3 dated 28 March 2023

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