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 9 December 2022 until 15 May 2025
and remains valid subject to satisfactory surveillance.
Issue 2. Certified since 16 May 2022
This certification is based on decision: FI22/08106P0

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 2

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: 5.0 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.

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The certification decision is based on the following:

Report	Identification	Date
QMS Audit Report	FIMED-c297111 DigiFinland Oy FPMDREG3019 - MDR Audit Report Ver D	2022-05-04
TDA Report	FIMEDc297111-DigiFinland Oy-FPMDREG3020 - MDR Technical Documentation Assessment Report Ver C	2022-05-13
TDA Extension Report	FIMEDc297111-DigiFinland Oy-FPMDREG3020 - MDR TDA Report Ver E	2022-12-02

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 Module 1 variant "Hampaiden tai suun alueen oire tai vamma -oirearvio"

Preceding certificate and its attachment 1
FI22/871876 issue 1 amended in Issue 2: Variant "Hampaiden tai suun alueen oire tai vamma -oirearvio" and related condition added

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09 December 2022 FI22/08106P0

Certification agreement MDR-2004-0 and notification of change dated 2022-08-10

Subject	Certification of the quality management system and product range concerning medical devices, based on Medical Device Regulation (EU) 2017/745 Annex IX, Chapters I and III including TDA as specified in Section 4. Extension of the scope of the certification according to the manufacturer's notification of change.
Manufacturer	DigiFinland Oy (FI-MF-000002451) Toinen linja 14, FI-00530 Helsinki, Finland
Decision	An amended certificate will be issued for the manufacturer. The details of the certified addresses, activities, devices and their intended purposes covered, risk classifications, standards and common specifications followed as well as applicable test and audit reports referred to, are listed in the Attachment 1 of the certificate. The certificate covers Omaolo version 5.0. Omaolo Module 1 variant "Hampaiden tai suun alueen oire tai vamma -oirearvio" is included in the certificate. The certificate is amended with the condition that a PMCF investigation (ref: Article 74(1)) is to be planned and conducted for the variant "Hampaiden tai suun alueen oire tai vamma -oirearvio" with scheduling requirements that are stated in the TDA extension report.
Justification	SGS Fimko Ltd has assessed manufacturer's quality management system and the technical documentation related to the change of the device. Quality management system and the technical documentation of the device meet the requirements of Annex IX of Medical Device Regulation (EU) 2017/745. The decision is based on the TDA extension report FIMEDc297111-DigiFinland Oy-FPMDREG3020 - MDR TDA Report Ver E 2022-12-02. The original certificate has been issued for five years based on the low-risk and established technology of the device. The original valid until date remains unchanged with this change assessment decision. The manufacturer has signed the undertaking to follow the obligations of Annex IX of the Regulation.
Certificate related to decision	FI22/871876 Issue 2
Valid until	This decision is valid until 15 May 2025 providing the requirements of the certification are fulfilled.
Date	Helsinki, 09 December 2022

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