DECISION

25 May 2021

FI21/07061P0

VitalSignum Oy
Kuortaneenkatu 2
FI-00510 Helsinki
Finland

EC certification application 18/079-1 dated 2019-10-04 and Notification of Change on 2021-01-13.

Subject	Extension of the scope of certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex II (excluding Section 4)
Manufacturer	VitalSignum Oy Kuortaneenkatu 2 FI-00510 Helsinki Finland
Decision	No change to the certificate. The proposed procedure pack, consisting of Beat2Phone ECG recorder and CE marked Cardiolyse ECG analyzing SW has been assessed and found to be in conformity with regulations. Because both components are CE marked and used in a compatible way, there is no need to update the certificate FI20/871798, Issue 1 to include the procedure pack. The certificate continues to cover the following product:

Product	Model	Class
ECG recorders	Consisting of Beat2Phone ECG Sensor and Beat2Phone ECG App version 2.X.X	IIa

Justification	SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex II (excluding Section 4) of Medical Device Directive 93/42/EEC. The decision is based on technical file review report 290458, dated 2021-05-25 and interpretation of MDD 93/42/EEC Article 12 (2). The manufacturer has signed the undertaking to follow the obligations of Annex II of the Directive 93/42/EEC.
Certificate related to decision	FI20/871798, Issue 1 (not changed)
Attachment to certificate	Attachment 1
Valid until	This decision is valid until 24 May 2024 providing the requirements of the certification are fulfilled.
Date	Helsinki, 25 May 2021

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