



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
217198-2017-AQ-RGC-NA-PS Rev. 2.0

Initial certification date:
02 December 2018

Valid:
03 December 2021 – 02 December 2024

This is to certify that the management system of
DFI Inc.

10F, No. 97, Sec. 1, Xintai 5th Rd.,
New Taipei City,
Taiwan

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design and Manufacture of Computer and PCBA for Medical Use.

Place and date:
Høvik, 23 September 2021



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer



Certificate no.: 217198-2017-AQ-RGC-NA-PS Rev. 2.0
Place and date: Høvik, 23 September 2021

Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
DFI Inc.	10F, No. 97, Sec. 1, Xintai 5th Rd., New Taipei City, Taiwan	Design of Computer and PCBA for Medical Use
DFI Inc.	No. 100, Huanhe St., Xizhi Dist., New Taipei City, Taiwan	Manufacture of Computer and PCBA for Medical Use