Declaration of Conformity (EU)

Manufacturer:	FLX Health
Manufacturer's address:	31-38 Queen Street, Hull, HU1 1UU
Company number:	12366748
Authorised representative:	Robert Lewis, Organisation Registered Number IE/CA01/R/GM/1569
AR address:	Arco Safety Limited, Ballymount Corporate Park, Ballymount Ave, Ballymount, Dublin, D12 HY11, Ireland
Basic UDI-DI:	Not assigned
GMDN code:	58884 (Self-care monitoring/reporting software)
Name of device:	FLX Health
Product code:	NA
Classification:	Class I
Notified Body:	NA (Class I)
NB address:	NA (Class I)
NB identification number:	NA (Class I)
Conformity assessment route:	FLX Health uses the following procedures for the CE mark of their products according the Regulation 93/42/EEC: Class I: EU conformity declaration according to Annex VII

This declaration of conformity is issued under the sole responsibility of FLX Health. We hereby declare that the medical device specified above meet the provision of the Regulation 93/42/EEC for medical devices. This declaration is supported by the FLX Health quality system.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

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Robert Lewis
Director and Authorised Representative

Date of issue:

29 June 2021

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Valid until 29 June 2024