


## Declaration of Conformity

<b>Manufacturer:</b>	FLX Health
<b>Manufacturer's address:</b>	31-38 Queen Street, Hull, HU1 1UU
<b>Company number:</b>	12366748
<b>Authorised representative:</b>	Robert Lewis
<b>AR address:</b>	31-38 Queen Street, Hull, HU1 1UU
<b>Basic UDI-DI:</b>	Not assigned
<b>GMDN code:</b>	58884 (Self-care monitoring/reporting software)
<b>Name of device:</b>	FLX Health
<b>Product code:</b>	NA
<b>Classification:</b>	Class I
<b>Notified Body:</b>	NA (Class I)
<b>NB address:</b>	NA (Class I)
<b>NB identification number:</b>	NA (Class I)
<b>Conformity assessment route:</b>	FLX Health uses the following procedures for the UKCA of their products according the Regulation 93/42/EEC:  <u>Class I:</u> UKCA 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:



Robert Lewis  
Director and Authorised Representative

Date of issue:

14 May 2021

Valid until 14 May 2024