



<b><u>UK Declaration of Conformity</u></b>	
Product Name	FreeStyle Libre 2 Flash Glucose Monitoring System (Sensor Kit)  FreeStyle Libre 2 Plus Flash Glucose Monitoring System (Sensor Kit)
Manufacturer	Abbott Diabetes Care Ltd. Range Road Witney, Oxfordshire, OX29 0YL, UK
First Date of UKCA Marking	28 September 2023
GMDN	44611

<b><u>The Medical Device Regulations 2002 (No.618)</u></b>	
Classification	IIb
Rule	Rule 10
Conformity Route per Part II (MDR 2002)	Annex II, Section 3
UK Approved Body	BSI Assurance UK Ltd.
UK Approved Body Identification No.	0086
UK Conformity Assessed (UKCA) Certificate	UKCA 776995

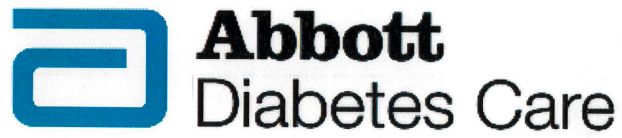
<b><u>The Radio Equipment Regulations 2017 (No 1206)</u></b>	
Designated Standards	EN 300 328 V2.2.2
Conformity Route	Module A

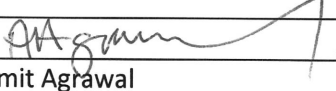
<b><u>The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (No 3032)</u></b>	
Designated Standards	EN IEC 63000:2018

Abbott Diabetes Care hereby declare that the above-mentioned product is in conformity with the following legislative acts:

- The Medical Device Regulation 2002 (No.618)
- The Radio Equipment Regulations 2017 (No 1206)
- The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (No 3032)

All supporting documentation is retained under the control of Abbott Diabetes Care Ltd. and made available for review upon request. This declaration is issued under the sole responsibility of, and signed on behalf of the legal manufacturer, Abbott Diabetes Care Ltd.



Signature	
Name	Amit Agrawal
Position	Regulatory Affairs Director, EMEAP
Place	Witney, UK
Date	04 - JANUARY - 2024 .

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