

Declaration of Conformity		
Product Name(s)	FreeStyle Precision Pro Blood Glucose and	
	β-Ketone Meter	
	FreeStyle Precision Pro Blood Glucose and	
	β-Ketone Monitoring System	
SKU	78286-01, 78285-01	
Manufacturer	Abbott Diabetes Care Ltd.	
	Range Road	
	Witney, Oxon,	
	OX29 0YL, UK	
First Date of UK Conformity Assessed	See date of signing	
(UKCA) Mark		
GMDN	62644	

The Medical Device Regulations 2002 (No.618)		
Classification	Self-declared	
Conformity Route	Annex III	

The Radio Equipment Regulations 2017 (No 1206)	
Designated Standards	EN 300 328 V2.2.2
	EN 301 893 V2.1.1
	EN 50566:2017
Conformity Route	Module A

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

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

- The Medical Device Regulations 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.

UKDEC008 REV-A

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Signature	Danielle M. Jewfor
Name	Danielle Taylor
Position	EMEA RA Director
Place	Witney UK
Date	26 May 2022

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