



HMD BioMEDICAL INC.

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European Representative: FIA Biomed GmbH
Rheiner Strasse 172, D-48282 Emsdetten, Germany

Your Partner in Blood Glucose Monitoring

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F-307

EC Declaration of Conformity

We, Manufacture, HMD Biomedical Inc.

of No.181, Minsheng Str., Xinpu Township, Hsinchu County 305, Taiwan

Our European Representative, FIA Biomed GmbH

of Rheiner Strasse 172, D-48282 Emsdetten, Germany

declare under our sole responsibility that the product

Trade name:	FIA Biomed™
Product Group:	Blood Glucose Meter
Product Model:	FIA Biomed Blood Glucose Monitoring System (Model No. Precisa)
Product Class:	Annex II, List B according to Council Directive 98/79/EC

to which this declaration relates is in conformity with the Annex I essential requirements and Annex IV relevant requirement of the IVDD Directive (98/79/EC). The product is compliant with the following standards and/or other normative documents:

EN ISO 13485:2016	IEC 62304: 2006+AMD1:2015
EN ISO 14971:2012	IEC 62366-1: 2015
EN ISO 15197:2015	EN ISO 18113-1, -4, -5:2011
EN 61010-1:2010	EN ISO 15223-1:2016
EN 61010-2-101:2017	EN 61326-2-6:2013
EN 60601-1-2:2015	EN 61326-1:2013
EN 13532:2002	EN 13612:2002
Directive 2012/19/EU (WEEE)	Directive 2011/65/EU (RoHS)

Certification No. and Notified Body: No. V1 097447 0006 Rev. 02

By  0123 / TÜV SÜD Product Service GmbH

Hsinchu, Taiwan

Mar 29, 2022

[Place, date]

Alex Hsu, Product Manager

Alex Hsu 2022
3/29

[Name and signature of person responsible]