



HMD BIOMEDICAL INC.

Http: //www.hmdbio.com

Your Partner in Blood Glucose Monitoring

European Representative: FIA Biomed GmbH

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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

<b>Trade name:</b>	FIA Biomed™
<b>Product Group:</b>	Blood Glucose Test Strip
<b>Product Model:</b>	FIA Biomed Blood Glucose Monitoring System (Model No. Precisa)
<b>Product Class:</b>	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	EN ISO 23640: 2015
EN ISO 14971:2012	EN ISO 18113-1, -4, -5:2011
EN ISO 15197:2015	EN ISO 15223-1:2016
IEC 62366-1: 2015	EN 13612:2002
EN 13532:2002	EN ISO 17511:2003
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]