DECLARATION OF CONFORMITY

Document No.: H1EN-CETF-011 Version 1.1

Manufacturer

HIPPO MEDICAL PTE. LTD.
60 PAYA LEBAR ROAD
#11-53 PAYA LEBAR SQUARE
SINGAPORE
SRN: SG-MF-000044482
ZIP Code: 409051
Email: info@hippodiabetes.com

Authorized Representative

PureCE B.V.
Distributieweg 13
2742 RB Waddinxveen
THE NETHERLANDS
Email: ear@purece.nl
Tel: +31108990449
SRN: NL-AR-000006069

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Object of the Declaration:
Device Type: Continuous Glucose Monitoring Device
Model: H1
Trade Name: Hippo H1
Trade mark: HiPPO BioSensors
Basic UDI-DI:8881300792H1KZ
Intended Purpose: The device is intended for the continuous monitoring of interstitial fluid glucose levels.
Other relevant data: The device consists of the following components: a sensor assembly, an applicator, a software application (App).

Classification: Class IIb according to Rule 10 of Annex VIII of Regulation (EU) 2017/745.
EMDN Code(s): Z1204011502 -INVASIVE BLOOD SUGAR MONITORING SYSTEMS

Conformity Statement:
The object of the declaration described above is in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Conformity with other Union Legislation:
The object of the declaration described above is also in conformity with the relevant provisions of the following Union legislation, where applicable:

- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), as amended.
- Regulation (EU) 2023/1542 concerning batteries and waste batteries (regarding incorporated batteries).
- Directive 2014/53/EU on radio equipment (regarding the incorporated touchscreen component).

Notified Body:
Name: IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.
Identification number: 0051
Conformity Assessment Procedure: Annex IX (Chapters I and III) of Regulation (EU) 2017/745.
Certificate Numbers: 225/MDR

Signed for and on behalf of: HIPPO MEDICAL PTE. LTD.

Place of Issue: Singapore
Date of Issue: 2025-06-24

Signature: _____

Name: Jiajia Xing
Title: Management Representative