

Declaration of Conformity

Manufacturer Name	SD Biosensor, Inc.
Manufacturer Address	<u>Head Office</u> C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, KOREA <u>Manufacturing Site</u> 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungchungbuk-do 28161, KOREA
EC Representative Name	MT Promedt Consulting GmbH
EC Representative Address	Altenhofstrasse 80 66386 St. Ingbert Germany
Product Category	Blood Glucose Monitoring System for self-testing
Model Name	STANDARD™ GlucoNavii® NFC <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>
Reference Number	01GM40, 01GS40 , 01GCH12, 01GCS20, 01GCS20-1, 01GCS20-2, 01GCS20-3
Classification	List B according to Annex II of Directive 98/79/EC
Conformity Assessment Route	Annex IV without section 4 and 6 of the IVDD 98/79/EC (Full Quality Assurance)
Notified Body	TÜV SÜD PRODUCT SERVICE GmbH
Notified Body Address	Ridlerstr. 65, 80339 München, Germany
ID Number of NB	0123
Number of EC-Certificate	V1 075369 0058 Rev. 03
EC-Certificate Issue Date	May 17, 2022
Applied Standards	EN ISO 13485:2016 EN ISO 18113-1:2011 EN ISO 14971:2012 EN ISO 18113-4:2011 EN ISO 15197:2015 EN ISO 18113-5:2011 EN ISO 23640:2015 EN 61010-2-101:2015 EN ISO 17511:2003 EN 13532:2002 EN ISO 15223-1:2016 EN 13612:2002

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentations are retained under the premises of the manufacturer. SD Biosensor, Inc. is exclusively responsible for the declaration of conformity.

Place: Suwon-si, Republic of Korea
Valid from: May 17, 2022

Signature



Hyo-Keun, Lee
CEO / President

Annex I. Product List

STANDARD™ GlucoNavii® NFC**Blood Glucose Monitoring System**

- STANDARD™ GlucoNavii® NFC Blood Glucose Meter (01GM40)
- STANDARD™ GlucoNavii® NFC Blood Glucose Test Strip (01GS40)
- STANDARD™ Glucose Check Strip (01GCH12)
- STANDARD™ GlucoNavii® Control Solution (01GCS20, 01GCS20-1, 01GCS20-2, 01GCS20-3)

EDMA Code

21 06 01

11.70.01.01.00

11.04.03.02.00

11 70 01 50 00

Description of EDMA code

Blood Glucose Meter

Glucose Test Strips

Glucose – Electrodes

Calibrators and Controls
(Blood Test Strips)