



Declaration of Conformity



Manufacturer Name SD Biosensor, Inc.

Manufacturer Address <u>Head Office</u>

C-4th&5th, 16, Deogyeong-daero, 1556beon-gil, Yeongtong-gu,

Suwon-si, Gyeonggi-do 16690, KOREA

Manufacturing Site

74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do 28161, KOREA

EC Representative Name MT Promedt Consulting GmbH

EC Representative Address Altenhofstrasse 80 66386 St. Ingbert Germany

Common Name Immunoassay Test Kit

Model Name STANDARDTM F H. pylori Ag FIA

*Please refer to "Annex I. Product List" on page 2 in more detail.

Reference Number F-HPY-01

Classification Others not covered by Annex II and self-testing according to

Directive 98/79/EC

Conformity Assessment Route Annex III of IVDD 98/79/EC (EC Declaration of Conformity)

Applied Standards EN ISO 13485:2016 EN ISO 18113-1:2011

EN ISO 14971:2012 EN ISO 18113-2:2011 EN ISO 23640:2015 EN ISO 15223-1:2016 EN ISO 17511:2003 EN 62366:2008

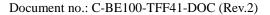
EN 13612:2002

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: January 13, 2022

Signature

Hyo-Keun, Lee CEO / President





Annex I. Product List

F-HPY-01 STANDARD TM F H. pylori Ag FIA	EDMA Code 15 01 04 01 00	Description of EDMA code H. Pylori Antigen Detection
- Test Device		
(individually in a foil pouch with desiccant)		
- Extraction buffer tube		
- Sterile swab (fecal)		
- Filter cap		
- Instructions for use		