Declaration of Conformity

CE

Manufacturer Name	SD Biosensor, Inc.
Manufacturer Address	*Head Office* C-4th&5th, 16, Deogyeong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA *Manufacturing Site* 14, Jeungpyeongsandan-ro, Jeungpyeong-eup, Jeungpyeong-gun, Chungcheongbuk-do 27915, REPUBLIC OF KOREA
EC Representative Name	MT Promedt Consulting GmbH
EC Representative Address	Ernst-Heckel-Straße 7 66386 St. Ingbert Germany
Common Name	Real Time PCR Test Kit
Product Name	**STANDARD™ M10 HPV** **Please refer to "Annex I. Product List" on page 2 in more detail.*
Reference Number	M10-HPV-01
Classification	Others not covered by Annex II and self-testing according to Directive 98/79/EC
Conformity Assessment Route	Annex III of Directive 98/79/EC (EC Declaration of Conformity)
Applied Standards	EN ISO 13485:2016 EN ISO 17511:2003 EN ISO 15223-1:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 14971:2012 EN 13612:2002 EN ISO 23640:2015 EN 62366:2008

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 20, 2022

Signature

Hyo-Keun, Lee
CEO / President

Annex I. Product List

	EDMA Code	Description of EDMA code
M10-HPV-01 **STANDARD™ M10 HPV** - Cartridge - Quick Reference Instructions	15 04 40 03 00	Human Papilloma Virus - NA Reagents

Annex II. Non-significant Change History

(After 26 May 2022)

#	Change Date	Change History	Remark
1	*8 February 2023*	*Change Address of EAR (EC-REP) and Manufacturing site*	*STANDARD™ M10 HPV*