Declaration of Conformity

Product Identification

MANUFACTURER: Seegene Inc.

Product : Allplex™ HPV HR Detection

Cat. Number : HP10370X, HP10376L, HP10371Z

EDMA code : 15 04 40 03 00 Human papilloma virus - NA Reagents

Manufacturer

Name: Seegene Inc.

Address : Taewon Bldg., 91, Ogeum-ro, Songpa-gu, Seoul, Republic of Korea, 05548

EU Authorized Representative

Name : Medical Technology Promedt Consulting GmbH

Address : Altenhofstrasse 80, D-66386 St.Ingbert, Germany

Standards Applied

EN 13612:2002, EN ISO 13485:2016, EN ISO 14971:2012 and others

Mean of Conformity

We, Seegene Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC in accordance with Annex III.

Product Classification

Other IVD/ Non-List A, Non-List B and not for self- testing

Signature

Date : May 13, 2022

Name : Jong-Yoon Chun/Top Management

Signature : 

Declaration of Conformity

Product Identification

MANUFACTURER: Seegene Inc.

Product : Allplex™ PneumoBacter Assay

Cat. Number : PB10176X, PB10175Y, PB10185Z

EDMA code : 15 01 01 90 00 : Other Chlamydia Reagents (CE_{2797})

15 01 05 40 00 : Legionella Detection by NA Reagents

15 01 08 40 00 : Mycoplasma Detection by NA Reagents

15 01 11 40 00 : Streptococci Detection by NA Reagents

15 01 40 07 00 : Bordetella pertussis/parapertussis – NA Reagents

15 01 40 10 00 : Haemophilus influenza – NA Reagents

Manufacturer

Name: Seegene Inc.

Address : Taewon Bldg., 91 Ogeum-ro, Songpa-Gu, Seoul, Republic of Korea 05548

EU Authorized Representative

Name : Medical Technology Promedt Consulting GmbH

Address : Altenhofstrasse 80, D-66386 St.Ingbert, Germany

Standards Applied

EN 13612:2002, EN ISO 13485:2016, EN ISO 14971:2012 and others

Mean of Conformity

We, Seegene Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC in accordance with Annex IV.

Product Classification

Annex II, List B

Certificate No. : CE572834 (Expiry date 25 November 2024)

Notified Body

Name : BSI Group The Netherlands B.V.

Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands.

Signature

Date : May 25, 2022

Name/Position : Jong-Yoon Chun/ Top Management

Signature : 

Seegene Inc.
Taewon Bldg. 91, Ogeum-ro, Songpa-gu, Seoul, 05548, Korea
Tel : +82-2-2240-4000 / Fax : +82-2-2240-4040

Identification of the Non-Significant Changes in the Device

Device Information:

No.	Name of the Device	Catalog number
1	Allplex™ PneumoBacter Assay	PB10176X, PB10185Z, PB10175Y

Summary of the Changes in the Device:

Date	Applied Section in MDCG 2022-6	Changes
23.12.19	4.2 Changes not concerning the design or intended purpose	Risk Management in accordance with EN ISO 14971:2019 Before: Standards Applied - EN ISO 14971:2012 After: Standards Applied - EN ISO 14971:2019
		Change of the address of European Authorized Representative Before: Altenhofstrasse 80, D-66386 St. Ingbert, Germany After: Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
		Symbols in the IFU and Label comply with EN ISO 15223-1:2021. Before: Standards Applied - EN ISO 15223-1:2016 After: Standards Applied - EN ISO 15223-1:2021
		Typographical error correction. - Correction of tube size errors in the raw material standard
		Update of the applied standards
		Diversification of stabilizer for control material

We, Seegene Inc., have carefully reviewed and evaluated these changes against the MDCG 2022-6, which provides clarification on significant changes under IVDR Article 110(3). This document identifies the non-significant changes made to the device which have no adverse impact on the device's intended purpose, design, operating principle, safety, and performance, and do not negatively affect the risk/benefit ratio of the device.

Person Responsible for Regulatory Compliance (PRRC) : Sung-il Ko

Date: 2023.12.19

Signature: Ko, Sung il

Declaration of Conformity

Product Identification

MANUFACTURER: Seegene Inc.

Product : Allplex™ RV Master Assay

Cat. Number : RV10307X, RV10363Z

EDMA code : 15 04 40 04 00: Influenza & Parainfluenza - NA Reagents

15 04 40 05 00: Respiratory syncytial virus - NA Reagents

15 04 40 01 00: Adenovirus – NA Reagents

15 04 40 90 00: Other Virology – NA Reagents

Manufacturer

Name: Seegene Inc.

Address : Taewon Bldg., 91, Ogeum-ro, Songpa-gu, Seoul, Republic of Korea, 05548

EU Authorized Representative

Name : Medical Technology Promedt Consulting GmbH

Address : Altenhofstrasse 80, D-66386 St.Ingbert, Germany

Standards Applied

EN 13612:2002, EN ISO 13485:2016, EN ISO 14971:2012 and others

Mean of Conformity

We, Seegene Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC in accordance with Annex III.

Product Classification

Other IVD/ Non-List A, Non-List B and not for self- testing

Signature

Date : May 20, 2022

Name : Jong-Yoon Chun/Top Management

Signature : 

Seegene
Seegene Inc. | Taewon Bldg. 91, Ogeum-ro, Songpa-gu, Seoul, 05548, Korea
Tel : +82-2-2240-4000 / Fax : +82-2-2240-4040

Identification of the Non-Significant Changes in the Device

Device Information:

No.	Name of the Device	Catalog number
1	Allplex™ RV Master Assay	RV10307X, RV10363Z

Summary of the Changes in the Device:

Date	Applied Section in MDCG 2022-6	Changes
23.12.19	4.2 Changes not concerning the design or intended purpose	Risk Management in accordance with EN ISO 14971:2019 Before: Standards Applied - EN ISO 14971:2012 After: Standards Applied - EN ISO 14971:2019
		Change of the address of European Authorized Representative Before: Altenhofstrasse 80, D-66386 St. Ingbert, Germany After: Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
		Symbols in the IFU and Label comply with EN ISO 15223-1:2021. Before: Standards Applied - EN ISO 15223-1:2016 After: Standards Applied - EN ISO 15223-1:2021
		Typographical error correction. - Correction of tube size errors in the raw material standard
		Update of the applied standards
		Diversification of stabilizer for control material

We, Seegene Inc., have carefully reviewed and evaluated these changes against the MDCG 2022-6, which provides clarification on significant changes under IVDR Article 110(3). This document identifies the non-significant changes made to the device which have no adverse impact on the device's intended purpose, design, operating principle, safety, and performance, and do not negatively affect the risk/benefit ratio of the device.

Person Responsible for Regulatory Compliance (PRRC) : Sung-il Ko

Date: 2023.12.19

Signature: 

Declaration of Conformity

Product Identification

MANUFACTURER: Seegene Inc.

Product : Allplex™ STI Essential Assay

Cat. Number : SD9801X, SD9801Y, SD10245Z

EDMA code : 15 01 01 40 00 : Chlamydia Detection by NA Reagents (CE2797)

15 01 08 40 00 : Mycoplasma Detection by NA Reagents

15 01 40 90 00 : Other Other Bacteriology – NA Reagents

Manufacturer

Name: Seegene Inc.

Address : Taewon Bldg., 91, Ogeum-ro, Songpa-gu, Seoul, Republic of Korea, 05548

EU Authorized Representative

Name : Medical Technology Promedt Consulting GmbH

Address : Altenhofstrasse 80, D-66386 St.Ingbert, Germany

Standards Applied

EN 13612:2002, EN ISO 13485:2016, EN ISO 14971:2012 and others

Mean of Conformity

We, Seegene Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC in accordance with Annex IV.

Product Classification

Annex II, List B

Certificate No. : CE572834 (Expiry date 26 May 2024)

Notified Body

Name : BSI Group The Netherlands B.V.

Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands.

Signature

Date : November 2, 2020

Name : Jong-Yoon Chun/Top Management

Signature : 

Declaration of Conformity

Product Identification

MANUFACTURER: Seegene Inc.

Product : STARMag 96 X 4 Universal Cartridge Kit

Cat. Number : 744300.4.UC384

EDMA code : 14 05 01 01 00 : Parasitology extraction reagents

Manufacturer

Name: Seegene Inc.

Address : Taewon Bldg., 91, Ogeum-ro, Songpa-gu, Seoul, 138-828, Korea

EU Authorized Representative

Name : Medical Technology Promedt Consulting GmbH

Address : Altenhofstrasse 80, D-66386 St.Ingbert, Germany

Standards Applied

EN 13612:2002, EN ISO 13485:2012, EN ISO 14971:2012 and others

Mean of Conformity

We, Seegene Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC in accordance with Annex III.

Product Classification

Other IVD/ Non-List A, Non-List B and not for self- testing

Signature

Date : May 10, 2016

Name : Jong-Yoon Chun

Signature : 

Atitikties deklaracija

Produkto identifikacija

GAMINTOJAS: Seegene Inc.

Produktas : STARMag 96 X 4 Universal Cartridge Kit

Kat. Nr : 744300.4.UC384

EDMA kodas : 14 05 01 01 00: Parazitologiniai ekstrakcijos reagentai

Gamintojas

Pavadinimas: Seegene Inc.

Adresas : Taewon Bldg., 91, Ogeum-ro, Songpa-gu, Seulas, 138-828, Korėja

Įgaliotas atstovas ES

Pavadinimas : Medical Technology Promedt Consulting GmbH

Adresas : Altenhofstrasse 80, D-66386 St.Ingbertas, Vokietija

Taikomi standartai

EN 13612:2002, EN ISO 13485:2012, EN ISO 14971:2012 ir kt.

Atitikties reikšmė

Mes, Seegene Inc., tvirtiname, kad aukščiau minimas produktas atitinka pagrindinius reikalavimus ir nuostatas, pateikiamas Tarybos direktyvoje dėl šalių narių įstatymų harmonizavimo dėl In-Vitro diagnostikos direktyvos 98/79/EC pagal III priedą.

Produkto klasifikacija

Kitas IVD/ Nėra sąraše A, nėra sąraše B, nėra skirtas savęs paties patikrai.

Parašas

Data : 2016 m. gegužės 10 d.

Vardas, Pavardė : Jong-Yoon Chun

Parašas : /parašas/

Tikslus dokumento vertimas į lietuvių kalbą
Vertėjas (-a) A. Gegelevičienė
Data: 2017-06-15
UAB Diamedica
Molėtų pl. 73, Vilnius
Lietuva
Tel. 8 5 279 0080

Declaration of Conformity

Product Identification

MANUFACTURER: Seegene Inc.

Product : Allplex™ GI-Bacteria (I) Assay

Cat. Number : GI9801X, GI9801Y

EDMA code : 15 01 10 40 00 : Salmonella Detection by NA Reagents

15 01 14 40 00 : Campylobacter Detection by NA Reagents

15 01 15 40 00 : E.coli Detection by NA Reagent

15 01 40 02 00 : Clostridium difficile – NA Reagents

15 01 40 06 00 : Yersinia – NA Reagents

15 01 40 14 00 : Shigella – NA Reagents

15 01 40 90 00 : Other Other Bacteriology – NA Reagents

Manufacturer

Name: Seegene Inc.

Address : Taewon Bldg., 91, Ogeum-ro, Songpa-gu, Seoul, 138-828, Korea

EU Authorized Representative

Name : Medical Technology Promedt Consulting GmbH

Address : Altenhofstrasse 80, D-66386 St.Ingbert, Germany

Standards Applied

EN 13612:2002, EN ISO 13485:2012, EN ISO 14971:2012 and others

Mean of Conformity

We, Seegene Inc. declared that the product listed above is in conformity with the essential requirements and provision of Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC in accordance with Annex III.

Product Classification

Other IVD/ Non-List A, Non-List B and not for self- testing

Signature

Date : May 11, 2015

Name : Jong-Yoon Chun

Signature :