Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Declaración pública respecto a la fabricación y uso de productos *in house*

Nombre del centro sanitario: CENTOGENE SPAIN S.L.U.

Dirección: Ronda Narcís Monturiol i Estarriol, 11 C (Parque Tecnológico), 46980 Paterna, Valencia, España.

CENTOGENE SPAIN S.L.U. declara que los productos incluidos en la tabla a continuación son fabricados y utilizados únicamente en CENTOGENE SPAIN S.L.U. y cumplen los requisitos generales de seguridad y funcionamiento (RGSF) aplicables establecidos en el Anexo I del Reglamento (UE) 2017/746, sobre los productos sanitarios para diagnóstico *in vitro*. Asimismo, se proporciona información sobre aquellos requisitos generales de seguridad y funcionamiento (RGSF) que no se satisfacen plenamente, junto con la correspondiente justificación motivada (en caso de que los haya).

Nombre, cargo y firma de la persona responsable de la actividad de fabricación in house (IH-IVD) en el centro sanitario:

Nombre: Alejandro Rincón Bertolín

Cargo: Persona Responsable de Productos In House

Lugar y fecha: _Paterna (Valencia, España), 04-11-2026

Firma: _____ **Firmado por:** Alejandro Rincon 594B6A5224F04AE...

Productos sanitarios para diagnóstico *in vitro in house* fabricados y utilizados en el centro sanitario

Servicio del centro sanitario	Identificación del producto (nombre, descripción y/o referencia)	Tipo de producto (PSDIV)	Clase	Finalidad prevista, usuarios y grupo de pacientes previstos	¿Se cumplen plenamente los RGSF aplicables en función del tipo de producto? (Sí/No)	RGSF aplicables que no se cumplen plenamente y justificación
Servicio de microbiología	CentoBiome: producto sanitario para diagnóstico in vitro de uso interno (IH-IVD), basado en qPCR, destinado a la detección y estimación semicuantitativa de un panel predefinido de microorganismos en muestras de fluido endometrial humano y a proporcionar información microbiológica complementaria	IH-IVD	C	CentoBiome detecta y estima de forma semicuantitativa un panel predefinido de microorganismos en fluido endometrial humano y clasifica el perfil microbiano endometrial conforme a criterios predefinidos. El resultado proporciona información microbiológica complementaria para apoyar la evaluación clínica y, cuando proceda, la decisión terapéutica por el profesional sanitario responsable en medicina	Sí	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Servicio del centro sanitario	Identificación del producto (nombre, descripción y/o referencia)	Tipo de producto (PSDIV)	Clase	Finalidad prevista, usuarios y grupo de pacientes previstos	¿Se cumplen plenamente los RGSF aplicables en función del tipo de producto? (Sí/No)	RGSF aplicables que no se cumplen plenamente y justificación
	para la evaluación clínica en medicina reproductiva. DC-537			reproductiva; no está destinado a utilizarse como prueba diagnóstica independiente ni a determinar automáticamente un tratamiento. Usuarios previstos: profesionales de laboratorio cualificados formados en diagnóstico molecular/qPCR y en el flujo CentoBiome; profesionales sanitarios cualificados que obtienen la muestra y profesionales cualificados con experiencia en ginecología y/o medicina reproductiva que interpretan el informe. Grupo de pacientes previsto: mujeres adultas en edad reproductiva sometidas a evaluación en medicina reproductiva, especialmente con fallo de implantación recurrente o pérdida gestacional recurrente, cuando el profesional sanitario responsable considere clínicamente indicada la evaluación del perfil microbiano endometrial. No está destinado al uso directo por pacientes ni a interpretación autónoma por personas no cualificadas.		
Servicio de genética reproductiva	PGT-M, incluyendo su fase preparatoria Pre-PGT-M: prueba genética molecular de diagnóstico in vitro de uso interno (IH-IVD), destinada al diagnóstico genético	IH-IVD	C	El PGT-M es un diagnóstico genético preimplantacional dirigido a una alteración genética familiar previamente identificada, como apoyo a la selección embrionaria previa a la transferencia en un programa de reproducción asistida. El Pre-PGT-M constituye la	Sí	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Servicio del centro sanitario	Identificación del producto (nombre, descripción y/o referencia)	Tipo de producto (PSDIV)	Clase	Finalidad prevista, usuarios y grupo de pacientes previstos	¿Se cumplen plenamente los RGSF aplicables en función del tipo de producto? (Sí/No)	RGSF aplicables que no se cumplen plenamente y justificación
	preimplantacional de enfermedades monogénicas cuando existe una alteración genética familiar previamente identificada. El Pre-PGT-M forma parte del mismo servicio y constituye la fase previa de diseño y validación analítica familiar específica. DC-689			fase preparatoria integrada en el mismo servicio, destinada al diseño, configuración y validación analítica familiar específica; no genera por sí mismo un resultado diagnóstico embrionario. Usuarios previstos: personal de laboratorio cualificado con experiencia en genética reproductiva, diseño de ensayos familiares específicos, análisis de ligamiento, PCR multiplex, electroforesis capilar y/o interpretación de datos genéticos embrionarios; y profesionales sanitarios cualificados implicados en reproducción asistida y/o asesoramiento genético. Grupo de pacientes previsto: personas o parejas sometidas a ciclos de FIV/ICSI cuando existe una variante genética familiar previamente identificada o un riesgo reproductivo genético conocido que justifica PGT-M. No está destinado al uso directo por pacientes o parejas ni a interpretación autónoma por personas no cualificadas.		
Servicio de genética reproductiva	PGT-A: prueba diagnóstica in vitro de genética molecular para uso interno (IH-IVD), destinada al cribado de aneuploidías cromosómicas embrionarias. DC-712	IH-IVD	C	PGT-A detecta alteraciones del número de copias cromosómicas en biopsias embrionarias, incluyendo aneuploidías cromosómicas completas, desequilibrios segmentarios dentro de la resolución analítica validada y, cuando proceda, estimación de mosaicismo, con el fin de apoyar la selección	Sí	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Servicio del centro sanitario	Identificación del producto (nombre, descripción y/o referencia)	Tipo de producto (PSDIV)	Clase	Finalidad prevista, usuarios y grupo de pacientes previstos	¿Se cumplen plenamente los RGSF aplicables en función del tipo de producto? (Sí/No)	RGSF aplicables que no se cumplen plenamente y justificación
				embrionaria en el contexto de FIV/ICSI. Usuarios previstos: personal de laboratorio cualificado y profesionales sanitarios cualificados implicados en reproducción asistida y/o asesoramiento genético. Grupo de pacientes previsto: personas o parejas sometidas a FIV/ICSI en las que se considera clínicamente indicado el cribado cromosómico embrionario. No está destinado al uso directo por pacientes ni a la interpretación autónoma por personas no cualificadas.		
Servicio de genética reproductiva	PGT-SR: prueba diagnóstica in vitro de genética molecular para uso interno (IH-IVD), destinada al cribado de desequilibrios cromosómicos segmentarios derivados de un reordenamiento estructural parental conocido, y de aneuploidías cromosómicas embrionarias. DC-731	IH-IVD	C	PGT-SR detecta desequilibrios cromosómicos segmentarios derivados de un reordenamiento estructural parental conocido, además de aneuploidías cromosómicas completas, para apoyar la selección de embriones sin desequilibrios cromosómicos detectables derivados del reordenamiento parental. Usuarios previstos: personal de laboratorio cualificado y profesionales sanitarios cualificados implicados en reproducción asistida y/o asesoramiento genético. Grupo de pacientes previsto: personas o parejas sometidas a FIV/ICSI cuando uno de los progenitores es portador conocido de un reordenamiento cromosómico estructural balanceado. No está destinado al uso directo	Sí	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Servicio del centro sanitario	Identificación del producto (nombre, descripción y/o referencia)	Tipo de producto (PSDIV)	Clase	Finalidad prevista, usuarios y grupo de pacientes previstos	¿Se cumplen plenamente los RGSF aplicables en función del tipo de producto? (Sí/No)	RGSF aplicables que no se cumplen plenamente y justificación
				por pacientes ni a la interpretación autónoma por personas no cualificadas.		
Servicio de genética reproductiva	CentoPGT-A: prueba diagnóstica in vitro de genética molecular para uso interno (IH-IVD), destinada al cribado de aneuploidías cromosómicas embrionarias, complementada con evaluación de ploidía, posible contaminación de origen materno o externo y concordancia entre biopsias de embriones hermanos de una misma cohorte. DC-746	IH-IVD	C	CentoPGT-A detecta alteraciones del número de copias cromosómicas en biopsias embrionarias, incluyendo aneuploidías cromosómicas completas, desequilibrios segmentarios dentro de la resolución analítica validada y, cuando proceda, estimación de mosaicismo. El servicio incluye una evaluación complementaria de ploidía, posible contaminación de origen materno o externo y concordancia entre biopsias de embriones hermanos de una misma cohorte, con el fin de apoyar la selección embrionaria en el contexto de FIV/ICSI. Usuarios previstos: personal de laboratorio cualificado y profesionales sanitarios cualificados implicados en reproducción asistida y/o asesoramiento genético. Grupo de pacientes previsto: personas o parejas sometidas a FIV/ICSI en las que se considera clínicamente indicado el cribado cromosómico embrionario y, cuando proceda, la evaluación complementaria de ploidía, posible contaminación de la muestra o concordancia entre biopsias embrionarias. No está destinado al uso directo por pacientes ni a la interpretación autónoma por personas no	Sí	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Servicio del centro sanitario	Identificación del producto (nombre, descripción y/o referencia)	Tipo de producto (PSDIV)	Clase	Finalidad prevista, usuarios y grupo de pacientes previstos	¿Se cumplen plenamente los RGSF aplicables en función del tipo de producto? (Sí/No)	RGSF aplicables que no se cumplen plenamente y justificación
				cualificadas.		
Servicio de genética reproductiva	CentoPGT-SR: prueba diagnóstica in vitro de genética molecular para uso interno (IH-IVD), destinada al cribado de desequilibrios cromosómicos segmentarios derivados de un reordenamiento estructural parental conocido y de aneuploidías cromosómicas embrionarias, complementada con evaluación de ploidía, posible contaminación de origen materno o externo y concordancia entre biopsias de embriones hermanos de una misma cohorte. DC-747	IH-IVD	C	CentoPGT-SR detecta desequilibrios cromosómicos segmentarios derivados de un reordenamiento estructural parental conocido, además de aneuploidías cromosómicas completas, para apoyar la selección de embriones sin desequilibrios cromosómicos detectables derivados del reordenamiento parental. El servicio incluye una evaluación complementaria de ploidía, posible contaminación de origen materno o externo y concordancia entre biopsias de embriones hermanos de una misma cohorte. Usuarios previstos: personal de laboratorio cualificado y profesionales sanitarios cualificados implicados en reproducción asistida y/o asesoramiento genético. Grupo de pacientes previsto: personas o parejas sometidas a FIV/ICSI cuando uno de los progenitores es portador conocido de un reordenamiento cromosómico estructural balanceado y, cuando proceda, se requiere evaluación complementaria de ploidía, posible contaminación de la muestra o concordancia entre biopsias embrionarias. No está destinado al uso directo por pacientes ni a la interpretación autónoma por personas no cualificadas.	Sí	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Servicio del centro sanitario	Identificación del producto (nombre, descripción y/o referencia)	Tipo de producto (PSDIV)	Clase	Finalidad prevista, usuarios y grupo de pacientes previstos	¿Se cumplen plenamente los RGSF aplicables en función del tipo de producto? (Sí/No)	RGSF aplicables que no se cumplen plenamente y justificación
Servicio de genética reproductiva	PGT-A High Definition: prueba diagnóstica in vitro de genética molecular para uso interno (IH-IVD), destinada al cribado de aneuploidías cromosómicas embrionarias. DC-501	IH-IVD	C	PGT-A High Definition detecta alteraciones del número de copias cromosómicas en biopsias embrionarias, incluyendo aneuploidías cromosómicas completas, desequilibrios segmentarios dentro de la resolución analítica validada y, cuando proceda, estimación de mosaicismo, con el fin de apoyar la selección embrionaria en el contexto de FIV/ICSI. Usuarios previstos: personal de laboratorio cualificado y profesionales sanitarios cualificados implicados en reproducción asistida y/o asesoramiento genético. Grupo de pacientes previsto: personas o parejas sometidas a FIV/ICSI en las que se considera clínicamente indicado el cribado cromosómico embrionario. No está destinado al uso directo por pacientes ni a la interpretación autónoma por personas no cualificadas.	Sí	N/A
Servicio de genética reproductiva	CentoPGT-A High Definition: prueba diagnóstica in vitro de genética molecular para uso interno (IH-IVD), destinada al cribado de aneuploidías cromosómicas embrionarias, complementada con evaluación de ploidía, posible contaminación de origen materno o externo y concordancia entre biopsias de	IH-IVD	C	CentoPGT-A High Definition detecta alteraciones del número de copias cromosómicas en biopsias embrionarias, incluyendo aneuploidías cromosómicas completas, desequilibrios segmentarios dentro de la resolución analítica validada y, cuando proceda, estimación de mosaicismo. El servicio incluye una evaluación complementaria de ploidía, posible contaminación de origen	Sí	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Servicio del centro sanitario	Identificación del producto (nombre, descripción y/o referencia)	Tipo de producto (PSDIV)	Clase	Finalidad prevista, usuarios y grupo de pacientes previstos	¿Se cumplen plenamente los RGSF aplicables en función del tipo de producto? (Sí/No)	RGSF aplicables que no se cumplen plenamente y justificación
	embriones hermanos de una misma cohorte. DC-748			materno o externo y concordancia entre biopsias de embriones hermanos de una misma cohorte, con el fin de apoyar la selección embrionaria en el contexto de FIV/ICSI. Usuarios previstos: personal de laboratorio cualificado y profesionales sanitarios cualificados implicados en reproducción asistida y/o asesoramiento genético. Grupo de pacientes previsto: personas o parejas sometidas a FIV/ICSI en las que se considera clínicamente indicado el cribado cromosómico embrionario y, cuando proceda, la evaluación complementaria de ploidía, posible contaminación de la muestra o concordancia entre biopsias embrionarias. No está destinado al uso directo por pacientes ni a la interpretación autónoma por personas no cualificadas.		

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Public Statement Regarding the Manufacture and Use of *In-House* Products

Name of healthcare institution: CENTOGENE SPAIN S.L.U.

Address: Ronda Narcís Monturiol i Estarriol, 11 C (Parque Tecnológico), 46980 Paterna, Valencia, Spain.

CENTOGENE SPAIN S.L.U. declares that the products included in the table below are manufactured and used exclusively within CENTOGENE SPAIN S.L.U. and comply with the applicable general safety and performance requirements (GSPR) set out in Annex I to Regulation (EU) 2017/746 on in vitro diagnostic medical devices. Information is also provided on those general safety and performance requirements (GSPRs) that are not fully met, together with the corresponding reasoned justification (where applicable).

Name, position and signature of the person responsible for the in-house (IH-IVD) manufacturing activity at the healthcare institution:

Name: Alejandro Rincón Bertolín

Position: In-House IVD Responsible Person

Place and date: Paterna (Valencia, Spain), 04-11-2026

Signature: _____ **Firmado por:** Alejandro Rincon 594B6A5224F04AE...

In-house in vitro diagnostic medical devices manufactured and used within the healthcare institution

Healthcare institution service	Product identification (name, description and/or reference)	Product type (IVD medical device)	Class	Intended purpose, intended users and intended patient population	Are the applicable GSPRs fully met according to the product type? (Yes/No)	Applicable GSPRs that are not fully met and justification
Microbiology service	CentoBiome: in-house in vitro diagnostic medical device (IH-IVD) based on qPCR, intended to detect and semi-quantitatively assess a predefined panel of microorganisms in human endometrial fluid samples and to provide complementary microbiological information for clinical assessment in reproductive medicine. DC-537	IH-IVD	C	CentoBiome detects and semi-quantitatively assesses a predefined panel of microorganisms in human endometrial fluid and classifies the endometrial microbial profile according to predefined criteria. The result provides complementary microbiological information to support clinical assessment and, where applicable, therapeutic decision-making by the responsible healthcare professional in reproductive medicine; it is not intended to be used as a stand-alone diagnostic test or to automatically determine	Yes	N/A

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Healthcare institution service	Product identification (name, description and/or reference)	Product type (IVD medical device)	Class	Intended purpose, intended users and intended patient population	Are the applicable GSPRs fully met according to the product type? (Yes/No)	Applicable GSPRs that are not fully met and justification
				treatment. Intended users: qualified laboratory professionals trained in molecular diagnostics/qPCR and in the CentoBiome workflow; qualified healthcare professionals who collect the sample; and qualified professionals experienced in gynaecology and/or reproductive medicine who interpret the report. Intended patient population: adult women of reproductive age undergoing assessment in reproductive medicine, particularly with recurrent implantation failure or recurrent pregnancy loss, when the responsible healthcare professional considers evaluation of the endometrial microbial profile clinically appropriate. Not intended for direct use by patients or for autonomous interpretation by unqualified individuals.		
Reproductive genetics service	PGT-M, including its preparatory Pre-PGT-M phase: in-house in vitro diagnostic molecular genetic test (IH-IVD), intended for preimplantation genetic diagnosis of monogenic disorders where a familial genetic alteration has previously been identified. Pre-PGT-M forms part of the same service and constitutes the family-specific analytical design and validation phase. DC-689	IH-IVD	C	PGT-M is a preimplantation genetic diagnosis targeting a previously identified familial genetic alteration, intended to support embryo selection prior to transfer in an assisted reproduction programme. Pre-PGT-M is the preparatory phase integrated into the same service, intended for family-specific analytical design, configuration and validation; it does not itself generate an embryonic diagnostic result. Intended users: qualified laboratory personnel with experience in reproductive genetics,	Yes	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Healthcare institution service	Product identification (name, description and/or reference)	Product type (IVD medical device)	Class	Intended purpose, intended users and intended patient population	Are the applicable GSPRs fully met according to the product type? (Yes/No)	Applicable GSPRs that are not fully met and justification
				design of family-specific assays, linkage analysis, multiplex PCR, capillary electrophoresis and/or interpretation of embryonic genetic data; and qualified healthcare professionals involved in assisted reproduction and/or genetic counselling. Intended patient population: individuals or couples undergoing IVF/ICSI cycles where a familial genetic variant has previously been identified or a known reproductive genetic risk justifies PGT-M. Not intended for direct use by patients or couples or for autonomous interpretation by unqualified individuals.		
Reproductive genetics service	PGT-A: in-house in vitro diagnostic molecular genetic test (IH-IVD), intended for the screening of embryonic chromosomal aneuploidies. DC-712	IH-IVD	C	PGT-A detects chromosomal copy number alterations in embryo biopsies, including whole-chromosome aneuploidies, segmental imbalances within the validated analytical resolution and, where applicable, mosaicism estimation, to support embryo selection in the context of IVF/ICSI. Intended users: qualified laboratory personnel and qualified healthcare professionals involved in assisted reproduction and/or genetic counselling. Intended patient population: individuals or couples undergoing IVF/ICSI for whom embryonic chromosomal screening is considered clinically indicated. Not intended for direct use by patients or for autonomous interpretation by unqualified individuals.	Yes	N/A
Reproductive	PGT-SR: in-house	IH-IVD	C	PGT-SR detects	Yes	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Healthcare institution service	Product identification (name, description and/or reference)	Product type (IVD medical device)	Class	Intended purpose, intended users and intended patient population	Are the applicable GSPRs fully met according to the product type? (Yes/No)	Applicable GSPRs that are not fully met and justification
genetics service	in vitro diagnostic molecular genetic test (IH-IVD), intended for the screening of segmental chromosomal imbalances resulting from a known parental structural rearrangement, and embryonic chromosomal aneuploidies. DC-731			segmental chromosomal imbalances resulting from a known parental structural rearrangement, in addition to whole-chromosome aneuploidies, to support the selection of embryos without detectable chromosomal imbalances resulting from the parental rearrangement. Intended users: qualified laboratory personnel and qualified healthcare professionals involved in assisted reproduction and/or genetic counselling. Intended patient population: individuals or couples undergoing IVF/ICSI where one parent is a known carrier of a balanced structural chromosomal rearrangement. Not intended for direct use by patients or for autonomous interpretation by unqualified individuals.		
Reproductive genetics service	CentoPGT-A: in-house in vitro diagnostic molecular genetic test (IH-IVD), intended for the screening of embryonic chromosomal aneuploidies, complemented by evaluation of ploidy, possible contamination of maternal or external origin, and concordance between biopsies of sibling embryos from the same cohort. DC-746	IH-IVD	C	CentoPGT-A detects chromosomal copy number alterations in embryo biopsies, including whole-chromosome aneuploidies, segmental imbalances within the validated analytical resolution and, where applicable, mosaicism estimation. The service includes a complementary evaluation of ploidy, possible contamination of maternal or external origin, and concordance between biopsies of sibling embryos from the same cohort, to support embryo selection in the context of IVF/ICSI. Intended users: qualified laboratory personnel and	Yes	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Healthcare institution service	Product identification (name, description and/or reference)	Product type (IVD medical device)	Class	Intended purpose, intended users and intended patient population	Are the applicable GSPRs fully met according to the product type? (Yes/No)	Applicable GSPRs that are not fully met and justification
				qualified healthcare professionals involved in assisted reproduction and/or genetic counselling. Intended patient population: individuals or couples undergoing IVF/ICSI for whom embryonic chromosomal screening and, where applicable, complementary evaluation of ploidy, possible sample contamination or concordance between embryo biopsies are considered clinically indicated. Not intended for direct use by patients or for autonomous interpretation by unqualified individuals.		
Reproductive genetics service	CentoPGT-SR: in-house in vitro diagnostic molecular genetic test (IH-IVD), intended for the screening of segmental chromosomal imbalances resulting from a known parental structural rearrangement and embryonic chromosomal aneuploidies, complemented by evaluation of ploidy, possible contamination of maternal or external origin, and concordance between biopsies of sibling embryos from the same cohort. DC-747	IH-IVD	C	CentoPGT-SR detects segmental chromosomal imbalances resulting from a known parental structural rearrangement, in addition to whole-chromosome aneuploidies, to support the selection of embryos without detectable chromosomal imbalances resulting from the parental rearrangement. The service includes a complementary evaluation of ploidy, possible contamination of maternal or external origin, and concordance between biopsies of sibling embryos from the same cohort. Intended users: qualified laboratory personnel and qualified healthcare professionals involved in assisted reproduction and/or genetic counselling. Intended patient population: individuals or couples undergoing IVF/ICSI where one parent is a known carrier of a	Yes	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Healthcare institution service	Product identification (name, description and/or reference)	Product type (IVD medical device)	Class	Intended purpose, intended users and intended patient population	Are the applicable GSPRs fully met according to the product type? (Yes/No)	Applicable GSPRs that are not fully met and justification
				balanced structural chromosomal rearrangement and, where applicable, complementary evaluation of ploidy, possible sample contamination or concordance between embryo biopsies is required. Not intended for direct use by patients or for autonomous interpretation by unqualified individuals.		
Reproductive genetics service	PGT-A High Definition: in-house in vitro diagnostic molecular genetic test (IH-IVD), intended for the screening of embryonic chromosomal aneuploidies. DC-501	IH-IVD	C	PGT-A High Definition detects chromosomal copy number alterations in embryo biopsies, including whole-chromosome aneuploidies, segmental imbalances within the validated analytical resolution and, where applicable, mosaicism estimation, to support embryo selection in the context of IVF/ICSI. Intended users: qualified laboratory personnel and qualified healthcare professionals involved in assisted reproduction and/or genetic counselling. Intended patient population: individuals or couples undergoing IVF/ICSI for whom embryonic chromosomal screening is considered clinically indicated. Not intended for direct use by patients or for autonomous interpretation by unqualified individuals.	Yes	N/A
Reproductive genetics service	CentoPGT-A High Definition: in-house in vitro diagnostic molecular genetic test (IH-IVD), intended for the screening of embryonic chromosomal aneuploidies,	IH-IVD	C	CentoPGT-A High Definition detects chromosomal copy number alterations in embryo biopsies, including whole-chromosome aneuploidies, segmental imbalances within the validated analytical resolution and, where	Yes	N/A

Proprietary Property of CENTOGENE SPAIN S.L.U.

Docusign Envelope ID: 286874F1-AF7E-87A2-834F-9505C832A2E6

Healthcare institution service	Product identification (name, description and/or reference)	Product type (IVD medical device)	Class	Intended purpose, intended users and intended patient population	Are the applicable GSPRs fully met according to the product type? (Yes/No)	Applicable GSPRs that are not fully met and justification
	complemented by evaluation of ploidy, possible contamination of maternal or external origin, and concordance between biopsies of sibling embryos from the same cohort. DC-748			applicable, mosaicism estimation. The service includes a complementary evaluation of ploidy, possible contamination of maternal or external origin, and concordance between biopsies of sibling embryos from the same cohort, to support embryo selection in the context of IVF/ICSI. Intended users: qualified laboratory personnel and qualified healthcare professionals involved in assisted reproduction and/or genetic counselling. Intended patient population: individuals or couples undergoing IVF/ICSI for whom embryonic chromosomal screening and, where applicable, complementary evaluation of ploidy, possible sample contamination or concordance between embryo biopsies are considered clinically indicated. Not intended for direct use by patients or for autonomous interpretation by unqualified individuals.		

Proprietary Property of CENTOGENE SPAIN S.L.U.

Certificate Of Completion

Envelope Id: 286874F1-AF7E-87A2-834F-9505C832A2E6
Status: Completed
Subject: Complete with Docusign: DC-677 Declaración IH-IVD Bilingual Master V1.0.pdf
Source Envelope:
Document Pages: 15
Signatures: 2
Certificate Pages: 4
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Enabled
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

Envelope Originator:
Jennifer Valero
Am Strande 7
Rostock , Mecklenburg-Western Pomerania 18055
Jennifer.Valero@centogene.com
IP Address: 185.72.2.24

Record Tracking

Status: Original
11/4/2026 9:19:44 AM
Holder: Jennifer Valero
Jennifer.Valero@centogene.com
Location: DocuSign

Signer Events	Signature	Timestamp
Alejandro Rincon Alejandro.Rincon@centogene.com COO Security Level: Email, Account Authentication (None)	Firmado por: Alejandro Rincon 594B6A5224F04AE...	Sent: 11/4/2026 9:21:15 AM Viewed: 11/5/2026 9:21:57 AM Signed: 11/5/2026 9:22:44 AM
	Signature Adoption: Pre-selected Style Using IP Address: 62.153.210.26	

Electronic Record and Signature Disclosure:
Accepted: 11/5/2026 9:21:57 AM
ID: 7b6a7abe-df82-4629-a701-d85b4204e616

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp
Belén Arnau Colomer belen.arnau@centogene.com Head QMRA Security Level: Email, Account Authentication (None)	COPIED	Sent: 11/4/2026 9:21:16 AM Viewed: 11/4/2026 10:07:07 AM

Electronic Record and Signature Disclosure:
Accepted: 10/20/2026 3:52:43 PM
ID: c0adc90c-5a9f-4e6d-83cc-70db7e50df68

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	11/4/2026 9:21:16 AM
Certified Delivered	Security Checked	11/5/2026 9:21:57 AM
Signing Complete	Security Checked	11/5/2026 9:22:44 AM
Completed	Security Checked	11/5/2026 9:22:44 AM

Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, CENTOGENE GmbH (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact CENTOGENE GmbH:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: legal@centogene.com

To advise CENTOGENE GmbH of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at legal@centogene.com and in the body of such request you must state: your previous

email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from CENTOGENE GmbH

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to legal@centogene.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with CENTOGENE GmbH

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to legal@centogene.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to ‘I agree to use electronic records and signatures’ before clicking ‘CONTINUE’ within the DocuSign system.

By selecting the check-box next to ‘I agree to use electronic records and signatures’, you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify CENTOGENE GmbH as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by CENTOGENE GmbH during the course of your relationship with CENTOGENE GmbH.