PUBLIC DECLARATION

Pursuant to Regulation (EU) 2017/746 (IVDR) on In vitro Diagnostic Medical Devices, Art. 5 (5) for In-House Manufacturing of IVD by Health Institutions

Health institution	**Medizinische Genetisches Zentrum** Bayerstrasse 3-5 80335 Munich Germany

We declare that the devices described below are only manufactured and used in our own premises on a non-industrial scale and comply with the applicable general safety and performance requirements (GSPR) of the IVD Regulation (EU) 2017/746, Annex I. A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Classification (Annex VIII):	Class C excluding self-/near-patient-testing
Device group (EMDN):	W01060101: Genetic testing of inborn gene or chromosome alterations for monogenic disorders
	W01060102: Genetic testing of inborn gene or chromosome alterations for polygenic disorders
	W02079092: Various general purpose IVD instruments- IVD medical device software
Intended purpose ((EU) 2017/2185):	IVR0403: Other devices intended to be used for human genetic testing
IVP code ((EU) 2017/2185):	IVP3011: In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)

Device designation:	**Device code:**	**Following GSPR do not apply:** See following checklists according tO Annex I
SBS short read exome sequencing	IVD-001	IVD-001-AI
Sanger sequencing	IVD-004	IVD-003-AI
Fragment length electrophoresis	IVD-006	IVD-006-AI
Nanopore long-read targeted repeats sequencing	IVD-007	IVD-007-AI
SBS short read genome sequencing	IVD-013	IVD-013-AI
SBS short read bisulfite sequencing	IVD-016	IVD-016-AI
Bisulfite methylation microarray analysis	IVD-017	IVD-017-AI

Name, function, signature of responsible person:	*Prof. Dr. med. Angela Abicht* Managing Director
Name, function, signature of responsible person:	*Dr. rer. nat. Soeren Schumacher* Deputy Managing Director

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Device designation:	Chromosomal microarray analysis
Device code:	IVD-003
Classification (Annex VIII):	Class C excluding self-/near-patient-testing
Device group (EMDN):	W01060103: Genetic testing of inborn gene or chromosome alterations for chromosomal disorders W02079092: Various general purpose IVD instruments- IVD medical device software
Intended purpose ((EU) 2017/2185):	IVR0401: Devices intended to be used in screening/confirmation of congenital/inherited disorders
IVP code ((EU) 2017/2185):	IVP3004: In vitro diagnostic devices which require knowledge regarding chromosomal analysis
Following GSPR do not apply:	see IVD-003-AI: Checklist *Compliance with Regulation (EU) 2017/746 Annex I*

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Name, function, signature of responsible person:	*Dr. rer. nat. Soeren Schumacher* Deputy Managing Director

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Device designation:	(Methylation-specific) Multiplex ligation-dependent probe amplification (MS) MLPA
Device code:	IVD-005
Classification (Annex VIII):	Class C excluding self-/near-patient-testing
Device group (EMDN):	W01060101: Genetic testing of inborn gene or chromosome alterations for monogenic disorders W01060102: Genetic testing of inborn gene or chromosome alterations for polygenic disorders W01060103: Genetic testing of inborn gene or chromosome alterations for chromosomal disorders W010602: Genetic testing of acquired gene or chromosome alterations W02079092: Various general purpose IVD instruments- IVD medical device software
Intended purpose ((EU) 2017/2185):	IVR0401: Devices intended to be used in screening/confirmation of congenital/inherited disorders
IVP code ((EU) 2017/2185):	IVP3011: In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Following GSPR do not apply:	see IVD-005-AI: Checklist *Compliance with Regulation (EU) 2017/746 Annex I*

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Device designation:	Haplotype analysis (karyomapping)
Device code:	IVD-008
Classification (Annex VIII):	Class C excluding self-/near-patient-testing
Device group (EMDN):	W01060101: Genetic testing of inborn gene or chromosome alterations for monogenic disorders W02079092: Various general purpose IVD instruments- IVD medical device software
Intended purpose ((EU) 2017/2185):	IVR0403: Other devices intended to be used for human genetic testing
IVP code ((EU) 2017/2185):	IVP3004: In vitro diagnostic devices which require knowledge regarding chromosomal analysis IVP3011: In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Following GSPR do not apply:	see IVD-008-AI: Checklist *Compliance with Regulation (EU) 2017/746 Annex I*

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Device designation:	SBS short read shallow genome sequencing: PGT-A / PGT-SR
Device code:	IVD-009
Classification (Annex VIII):	Class C excluding self-/near-patient-testing
Device group (EMDN):	W01060103: Genetic testing of inborn gene or chromosome alterations for chromosomal disorders
	W02079092: Various general purpose IVD instruments- IVD medical device software
Intended purpose ((EU) 2017/2185):	IVR0403: Other devices intended to be used for human genetic testing
IVP code ((EU) 2017/2185):	IVP3004: In vitro diagnostic devices which require knowledge regarding chromosomal analysis
	IVP3011: In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Following GSPR do not apply:	see IVD-009-AI: Checklist *Compliance with Regulation (EU) 2017/746 Annex I*

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Device designation:	SBS short read targeted duplex sequencing
Device code:	IVD-012
Classification (Annex VIII):	Class C excluding self-/near-patient-testing
Device group (EMDN):	W01060101: Genetic testing of inborn gene or chromosome alterations for monogenic disorders W01060102: Genetic testing of inborn gene or chromosome alterations for polygenic disorders W010602: Genetic testing of acquired gene or chromosome alterations W02079092: Various general purpose IVD instruments- IVD medical device software
Intended purpose ((EU) 2017/2185):	IVR0403: Other devices intended to be used for human genetic testing
IVP code ((EU) 2017/2185):	IVP3011: In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Following GSPR do not apply:	see IVD-012-AI: Checklist *Compliance with Regulation (EU) 2017/746 Annex I*

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Device designation:	Droplet digital PCR
Device code:	IVD-014
Classification (Annex VIII):	Class C excluding self-/near-patient-testing
Device group (EMDN):	W010602: Genetic testing of acquired gene or chromosome alterations W02079092: Various general purpose IVD instruments- IVD medical device software
Intended purpose ((EU) 2017/2185):	IVR0403: Other devices intended to be used for human genetic testing
IVP code ((EU) 2017/2185):	IVP3011: In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Following GSPR do not apply:	see IVD-014-AI: Checklist *Compliance with Regulation (EU) 2017/746 Annex I*

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Device designation:	Optical genome mapping (OGM)
Device code:	IVD-015
Classification (Annex VIII):	Class C excluding self-/near-patient-testing
Device group (EMDN):	W01060101: Genetic testing of inborn gene or chromosome alterations for monogenic disorders W01060102: Genetic testing of inborn gene or chromosome alterations for polygenic disorders W01060103: Genetic testing of inborn gene or chromosome alterations for chromosomal disorders W02079092: Various general purpose IVD instruments- IVD medical device software
Intended purpose ((EU) 2017/2185):	IVR0403: Other devices intended to be used for human genetic testing
IVP code ((EU) 2017/2185):	IVP3004: In vitro diagnostic devices which require knowledge regarding chromosomal analysis
Following GSPR do not apply:	see IVD-015-AI: Checklist *Compliance with Regulation (EU) 2017/746 Annex I*

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