
FB-IVDR-001 Declaration

Public declaration regarding the manufacture and use of in-house devices by health institutions under Art. 5 (5) EU Regulation on in vitro diagnostic medical devices (EU) 2017/746 (IVDR) for in-house production of IVD in health institutions and under Art. 5 (5) EU Regulation on medical devices (EU) 2017/745 (MDR) for in-house production of MD in health institutions

Name of health institution: Labor-Dr. Wisplinghoff

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Labor Dr. Wisplinghoff declares that the devices described in the accompanying table are manufactured and/or used at *Labor Dr. Wisplinghoff* and do meet the applicable general safety and performance requirements (GSPR) of the medical devices Regulation (EU 2017/745) or of the *in vitro* diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Name, function and signature of responsible person(s):

Dr. rer. nat. Dennis Hoffmann

Technical Director

	Date	Signature
Approval by Technical Director	22.09.2026	Hoffmann, Dennis

FB-IVDR-001 Declaration

Table of in-house devices:

Device identification	Device type (IVD/ MD)	Risk class of the device	Intended purpose	Applicable GSPR fully met?	Information on and justification for applicable GSPR that are not fully met
APS (edta-plasma) via LC/MS/MS	IVD	B	Patient health data	Y	NA
Serotonin (serum) via LC/MS/MS	IVD	B	Patient health data	Y	NA
5-HIAA (plasma) via LC/MS/MS	IVD	B	Patient health data	Y	NA
Analysis of human genetic diseases via MLPA (multiplex ligation-dependent probe amplification)	IVD	C	Patient health data	Y	NA
Analysis of human genetic diseases via Sanger sequencing	IVD	C	Patient health data	Y	NA
Analysis of human genetic diseases via Pyrosequencing	IVD	C	Patient health data	Y	NA
Determination of chromosomal and genomic imbalances via array CGH	IVD	C	Patient health data	Y	NA
Determination of chromosomal and genomic imbalances via next generation sequencing (NGS) (Illumina)	IVD	C	Patient health data	Y	NA
Whole exome sequencing (WES) via NGS (Illumina)	IVD	C	Patient health data	Y	NA
Oncomine Focus Panel diagnostics via NGS (IonTorrent)	IVD	C	Patient health data	Y	NA

FB-IVDR-001 Declaration

Device identification	Device type (IVD/ MD)	Risk class of the device	Intended purpose	Applicable GSPR fully met?	Information on and justification for applicable GSPR that are not fully met
Somatic tumor diagnostics via NGS (IonTorrent)	IVD	C	Patient health data	Y	NA
Interpretation of metagenomic next-generation sequencing (mNGS) data for pathogen detection from cell-free DNA using the DISQVER® bioinformatics platform (Bruker).	IVD	C	Patient health data	N	Analytical performance has been validated, and the test has been in routine clinical use for two years. Following Bruker's acquisition of the platform, the previously IVD-conforming DISQVER® is currently supplied under RUO designation; IVD conformity assessment is in progress. The analytical algorithm is unchanged. Continued use is governed by documented risk management.