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
Address: Horbeller Str. 18 – 20, 50858 Köln, Germany

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.

Date: 24. Juli 2025

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

Dr. rer. nat. Dennis Hoffmann

Technical Director

	29.07.2025
Signed	**Dated**

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
Serotonin (serum) vía 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 imblances via array CGH	IVD	C	Patient health data	Y	NA
Determination of chromosomal and genomic imblances via next generation sequencing (NGS) (Ilumina)	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
Somatic tumor diagnostics via NGS (IonTorrent)	IVD	C	Patient health data	Y	NA