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

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MLM Medical Labs GmbH declares that the devices described in the accompanying table are only manufactured and used in MLM Medical Labs GmbH 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.

Moenchengladbach, 31 October 2025

Dr. Stephan Voswinkel

Managing Director

Table of in-house devices:

Device identification	Device type (IVD/MD)	Risk class	Intended purpose	Applicable GSPR fully met? (Y/N)	Information on and justification for applicable GSPR that are not fully met
Lumipulse® G KL-6 P	IVD	C	Patient health data	Y	na
Lumipulse® G Tau217/Aß42 Plasma Ratio	IVD	C	Patient health data	Y	na