Public declaration under Art 5 (5) EU Regulation on in vitro diagnostics medical device (EU 2017/746 (IVDR) for in-house production of IVD in health institutions

MLM Medical Labs GmbH
Dohrweg 63
41066 Moenchengladbach

MLM Medical Labs GmbH declares under its sole responsibility, that the products listed below, which are manufactured by us as in-house products, comply with all applicable **General Safety and Performance Requirements(GSPR)** of the **medical devices regulation (EU2017/745**) or the **IVD Regulation (EU) 2017/746, Annex 1 – 'General Safety and Performance Requirements'.**
A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Moenchengladbach, 15 March 2024

Dr. Stephan Voswinkel

Managing Director

Table of in-house products:

Product	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	IVD	C	The Lumipulse® G KL-6 is an in vitro diagnostic immunoassay intended for the quantitative determination of the sialylated carbohydrate antigen, KL-6 in human serum or plasma, as a supportive biomarker for prognosis of disease progression in adult subjects with Interstitial Lung Diseases (ILDs), either idiopathic or related to connective tissue diseases.	Y	na