EUROIMMUN Medizinische Labordiagnostika AG

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Statement

EUROIMMUN Medizinische Labordiagnostika AG declares that all IVDD-*Legacy Devices* meet the demands of Directive 98/79/EC (IVDD) based on conformity assessment procedure according to annex III. This remains valid on basis of article 110 (3) of the Regulation (EC) 2017/746 (IVDR).
However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply and replace the corresponding requirements in Directive 98/79/EC.

IVDD-*Legacy devices* are exempted from the Regulation (EC) No 1272/2008 (CLP) as stated in *article 1*, section 5 (d).

Therefore, classification and labelling obligations according to CLP and subsequently the requirements of regulation (EC) No 1907/2006 (REACh) regarding safety data sheets are not applicable.

Lübeck, 18.01.2023

Sven Bajorat
Head of Division Quality Management and Regulatory Affairs