EUROIMMUN
a PerkinElmer company

Medizinische
Labordiagnostika
AG

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Confirmation

EUROIMMUN Medizinische Labordiagnostika AG declares that this in-vitro diagnostic medical device (IVD) is subjected to the scope of the EC directive No 98/79/EC (IVDD). In-vitro diagnostic products according to IVDD are exempted from the regulation (EC) No 1272/2008 (CLP) as stated in TITLE 1, *article 1*, section 5 (d). Hence, no assessment and labelling obligations according to CLP are required.

The assessment and labelling obligations according to the regulation (EC) No 1907/2006 (REACh) is the condition for placing an IVD on the market with a safety data sheet. Because of the mentioned exemption this condition for the corresponding IVD is not given.
Hence, safety data sheets according to the regulation (EC) No 1907/2006 are not needed.

Lübeck, 12. APR. 2022

Chairman of the Executive Board