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# EC DECLARATION OF CONFORMITY

**according to Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices**

We, **DRG Instruments GmbH**, Frauenbergstr. 18, 35039 Marburg, Germany

herewith declare under our own responsibility that the products listed in the table below,

**which are classified as m i s c e l l a n e o u s p r o d u c t s**

are in accordance with the requirements of the IVD Directive 98/79/EC annex I and III of the European Parliament in regard to the in vitro diagnostic medical devices (IVDs) and therefore are allowed to be CE signed.

Quality Management

DRG Instruments GmbH has established a Quality Management System for the design/development, production and distribution of in vitro diagnostic according to DIN EN **ISO 13485:2016**.

Marburg, 2019-08-01

Wilhelm Sänger
General Manager

Dr. Bernd Röder
Head of Regulatory Affairs

| ***Product name*** | ***DRG Cat.-No*** |
|---|---|
| Anti-LKM-1 ELISA | EIA-4277 |



**DRG Instruments GmbH**
**Geschäftsführer:**
**Wilhelm Sänger**
**Sitz: Marburg, HRB 1165**