

Certificate of CE-Registration



This is to certify that, in accordance with Regulation (EU) 2017/746 on in vitro diagnostic medical devices, mdi Europa GmbH, SRN DE-AR-000006218 agree to perform all duties and responsibilities as the Authorized Representative for

Labcon North America
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CA 94954-5671 Petaluma
USA

as stipulated and demanded by the afore-mentioned Regulations. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

EDMA Code	Description / Basic UDI-DI	Classification	Registration Number
21.01.10.01	CH Hardware + dedicated accessories + software	other IVD	DE/CA09/00089590
24.09	Other Microbiology	other IVD	DE/CA09/00022135

The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC as amended by 2007/47/EC or 98/79/EC.

Signed on 06 October 2022

Werner Sander
President