



MDSS GmbH · Schiffgraben 41 · 30175 Hannover · Germany

Biomerica, Inc.
Mr. Roland Strickland
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USA

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2020.03.18

Confirmation of CE Notification p109691

Dear Roland,

We confirm that MDSS has submitted the following IVD notification to the German Competent Authority. Please note, the notification(s) were performed under § 25 MPG. (MPG - Medizinproduktegesetz). This is the Federal Republic of Germany's national transposition of IVDD 98/79/EC.

Device Nomenclature	Code	Description	Classification	Device Name
EDMA	15 70 90 90	Other Other Virology - RT & POC	"Other IVD"	COVID-19 IgG/IgM Rapid Test

The notification requirements of the IVD Directive 98/79/EC, articles 10.1 & 10.3 are fulfilled with the submission of the notification. The transitional provision of art. 10.6 of the IVD Directive which obliged IVD manufacturers to give notification to each & every European Member State concerned by IVD sales ceased to apply with the implementation of EUDAMED in May 2011. For this reason MDSS will not submit further notifications to other European countries on behalf of Biomerica, Inc. at this time. However, keep in mind that some countries may have additional national level registration requirements. Please let us know if you would like MDSS to handle a national level registration.

Please keep in mind that MDSS should always be informed of the following:

- Affixing of CE mark to new products (registration may need to be done)
- Significant changes affecting previously submitted product notifications. For example:
 - Change in company name or address
 - Change to device/name make
 - Changes in intended use, performance characteristics, risk class,
 - Changes relevant to EC Certificate
- Discontinuation of previously notified products
- Incidents or Field Safety Corrective Actions as per MEDDEV Guidelines and the IVDD 98/79/EC

MDSS GmbH · Medical Device Safety Service GmbH

Handelsregister Hannover HRB 57318 · Amtsgericht Hannover
Trade Register Hannover HRB 57318 · Local Court Hannover

Sparkasse Hannover

S.W.I.F.T.: SPKDHDE2H
IBAN: DE24 2505 0180 0910 0792 77

USt-IdNr: DE177346163
VAT ID: DE177346163

Geschäftsführer: Ludger Möller
President: Ludger Möller

Commerzbank AG, Hannover

S.W.I.F.T.: COBADEFF 250
IBAN: DE67 2504 0066 0338 8816 00





Upon release of the German registration number(s), MDSS issues a "Certificate of CE Registration" summarizing the German registration/notifications performed by MDSS on behalf of your company. We remind you that all products must meet the applicable provision of the European and national regulations before they made available to the market (e.g. language requirements for labeling and instructions for use).

Best regards,
Joy Grimm
Senior Consultant
Medical Device Safety Service GmbH

This document is valid without a signature and is electronically traceable in the MDSS system.