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BTNX, Inc.
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Confirmation of CE Notification p112148

Dear Khasim,

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

EDMA Code	EDMA Description	Classification	Notified Device Names (device names marked in blue were added to existing registration(s);
15 70 90 90	Other Other Virology - RT & POC	"Other IVD"	Rapid Response™ COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma); Rapid Response™ COVID-19 IgG/IgM Rapid Test Device; Rapid Response™ Liberty COVID-19 IgG/IgM Test (Whole Blood/Serum/Plasma); Rapid Response™ COVID-19 Antigen Test Cassette; Rapid Response™ COVID-19 Antigen Rapid Test Device; Rapid Response™ COVID-19 Antigen Rapid Test Cassette; Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Saliva); Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Saliva/Nasopharyngeal Swab)

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 BTNX, 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

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,

Brigitta Révész-Walker
Registration Dept.
Medical Device Safety Service GmbH

This verification letter is valid without signature. The document can be traced within MDSS' electronic system.