MEDeviCE Group SIA

Your authorized partner for Medical device registration

CERTIFICATE
OF
MEDICAL DEVICE NOTIFICATION

Our Ref. Nr.: CMDN-0002
Place of issue: Riga, Latvia
Date: 26rd of March 2020

By this certificate, we, MEDeviCE Group SIA, located at Jurmalas gatve 32, Riga, Latvia, LV-1067, authorized representative for Medical and IVD product registration, hereby confirm that company BOSTON BIO LAB INC, legal address - 1395 Brickell ave.#800, Miami, FL 33131 USA, has obtained registration acknowledgment in LATMED and EUDAMED databases from State Agency of Medicines Republic of Latvia Nr. 7-1/68 from 26.03.2020 as Manufacturer of IVD Medical device (see Annex I) Class "Others" according to EU IVD Medical Device Directive 98/79/EK.

All notification procedures for obtaining Class "Others" IVD Medical devices registration was performed by MEDeviCE Group SIA on 24.03.2020 to national Competent Authority "State Agency of Medicines Republic of Latvia".

As of the 26.03.2020, and as long as the manufacturer will continue to comply with hereabove mentioned requirements he therefore:

- Is required to affix the CE marking on the devices as per Annex I to this certificate
- May place these devices on the market of European Union
- May issue EC declaration of conformity using CE mark as per EU IVD Medical Device Directive 98/79/EK.

Andrejs Gaivoronskis
CEO
MEDeviCE Group

CE

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ANNEX I TO CERTIFICATE OF MEDICAL DEVICE NOTIFICATION

Our Ref. Nr.: CMDN-0002
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Nr.	Generic device term	Commercial name	Class*	Catalog reference nr (UDI)	Short description and intended use	GMDN/UMDNS code**
1.	COVID-19 Home Test Kit for detection of IgM antibody of SARS-CoV-2	COVID-19 Home Test Kit for detection of IgM antibody of SARS-CoV-2	Class "Others" IVD Medical device according to EU Medical Device Directive 98/79/EK	0850017675018	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of immunoglobulin M (IgM) antibodies to severe acute respiratory syndrome-associated coronavirus (SARS-CoV) in a clinical specimen, using an enzyme immunoassay (EIA) method.	

* - Hereabove product list classification is based on the classification claim of the manufacturer and under its own responsibility (MD 93/42/EEC as modified by 2007/47/EC)
** - GMDN/UMDNS code is mandatory information to complete Notification.
*** - device unique serial number for individual device identification.

Manufacturer: BOSTON BIO LAB Inc.
Signature:

Date: 26/03/2020
Place: Miami/Florida

MEDeviCE Group SIA
Signature.

Date:26/03/2020
Place: Riga, Latvia.

CE