EC Declaration of Conformity

Manufacturer:

Name: Inzek International Trading
Address: Vissenstraat 32, 7324AL – Apeldoorn, The Netherlands

Product Name and Models(s):

COVID-19 IgM/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

REF BNCP-402

Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III
EDMA Code: 15 70 90 90 00

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on *in vitro* diagnostic medical devices

Standard Applied: EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN ISO, EN 13641:2002, ISO 15223-1:2012

CE After preparation of the necessary technical documentation as well as the conformity declaration the required CE marking can be affixed on the product. Other relevant directives must be observed.

Place, Date of Issue: Apeldoorn on 20/02/2020

Signature: _____

Name: Z. Hamid

Position: Manager