EC Declaration of Conformity

Manufacturer:

Name: Inzek International Trading
Address: Laan van de ram 49- 7324BW – Apeldoorn, The Netherlands

This declaration of conformity is issued under the sole responsibility of the legal manufacturer Inzek International Trading B.V.

Product Name and Models(s):

COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal swab)

REF: BCOV-502

Classification:

After following the classification rules of Annex II of the COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning in vitro diagnostic medical devices, the device listed in this declaration was classified as a non-listed in vitro diagnostic medical device.

Conformity statement:

According to Article 9 of the COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning in vitro diagnostic medical devices, and based on the classification of the product, the manufacturer, in order to affix the CE marking, followed the procedure referred to in Annex III, of the directive.

Notified body:

Not applicable, as a non-listed in vitro diagnostic medical device does not require the involvement of a Notified Body

Place, Date of Issue: Apeldoorn on 06/10/2020

Signature:

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Position: Manager

Zertifikat – Certificate – Certificat – Certificado – Certificat – Sertifika – شهادة – сертификат - Certifik