CE

Declaration of Conformity

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: ZandCell AB
Address: Locketorp Liden 2, 54191 Skövde, Sweden

European Representative:
Name: ZandCell AB
Address: Locketorp Liden 2, 54191 Skövde, Sweden

Product Name: ZandCell COVID-19 Rapid Antigen Test
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding point 6)
EDMA Code: 15 70 90 90 00

We, ZandCell AB, herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

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 ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011

michael zand

Michael Zand – CEO ZandCell AB

Date: 11 September, 2020
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