EC Declaration of Conformity

Manufacturer: Shenzhen Watmind Medical Co., Ltd.
Address:
8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community, Kengzi Subdistrict, Pingshan District, 518118, Shenzhen, China

EC-Representative:
Name: Shanghai International Holding Corporation GmbH(Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name:
SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)
REF: LFA0401-1N, LFA0401-5N，LFA0401-25N
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III

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

DIRECTIVES

General Applicable Directive:
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 13485:2016,EN ISO 14971:2012,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,EN13641:2002,EN ISO 15223-1:2016.

Place,Date of Issue: in Shenzhen on 11th,March,2020

Li Quan
General Manager

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