CE

EC Declaration of Conformity

Manufacturer:
Name: Madison Medical s.r.o.
Adress: U Svitavy 1077/2, Černovice, 618 00 Brno, Czech republic

Product Name: Yannovak – Rapid test for the detection of post-vaccination and post-covid antibodies of COVID-19

Model: Cassette
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 08 00

We, Madison Medical s.r.o., 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 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, EN 13641:2002, EN ISO 15223-1:2016

Place, Date: Brno, 3/11/2021

Signature:

Name: Jaroslav Kalina

Position: CEO