CE

EC Declaration of Conformity

Manufacturer: Oncosem Onkolojik Sistemler San. Ve Tic. A.Ş.

Address: Mustafa Kemal Mah. 2125 Sokak A Blok No: 6/8 Sogutozu 06520 Ankara Turkiye

Product Name : 2019-nCoV Antigen Rapid Test Kit

Model : Single Use Test Kit
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, Oncosem Onkolojik Sistemler San. Ve Tic. A.Ş., 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 provsions 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 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 of Issue: Ankara Turkey on October 20th, 2020

NAME: EROL ÇELİK – GENERAL MANAGER

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