## (GB)

## **EU DECLARATION OF CONFORMITY**

This Declaration of Conformity, issued under the sole responsibility of the manufacturer

3M United Kingdom PLC of 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT, UK

hereby declaring the following Personal Protective Equipment (PPE)

Product Description: 3M™ Aura™ Health Care Respirators

Product Model: 1861+, 1862+, 1863+ and 1883+

is/are in conformity with the provisions of the following European Regulations

## PPE (Personal Protective Equipment) Regulation

The model is/are in conformity with the provisions of Regulation (EU) 2016/425, including fulfilment of the applicable essential health and safety requirements set out in Annex II, and with the National Standard transposing the harmonised European Standard Number(s):

EN 149:2001+A1:2009

and is/are identical to the PPE which is/are the subject of EU type-examination (Module B of Regulation (EU) 2016/425) referenced on the certificate number:

CE 682245 (Issue Date: 19/11/2020)

issued by

BSI Group, The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Notified Body No. 2797

and is/are subject to the procedures set out in Module D of Regulation (EU) 2016/425 under the surveillance of:

BSI Group, The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Notified Body No. 2797

## **Medical Device Regulation**

Basic UDI-DI: 0608223826106000000001KT

The model(s) is/are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class 1 devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices and with the National Standard transposing the harmonised European Standard Number(s):

EN 14683:2019+AC:2019

The Authorized European Representative for the concerned device(s) is 3M Deutschland GmbH, Health Care Business, Carl-Schurz-Str. 1, 41453 Neuss, Germany

Signed by: M Thomas

European Regulatory Manager Personal Safety Division 3M United Kingdom PLC

Date: 20th November 2020

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