



## DECLARATION OF CONFORMITY

Regulation 2016/425 on personal protective equipment, as amended to apply in GB

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/s: 1861+, 1862+, 1863+ and 1883+**

is/are in conformity with the provisions of the following Regulations and/or Directives

### **PPE (Personal Protective Equipment Regulation)**

The model is/are in conformity with the provisions of the Regulation 2016/425 on personal protective equipment, as amended to apply in GB, including fulfilment of the applicable essential health and safety requirements set out in Annex II, and with the Standard Number(s):

**EN 149:2001+A1:2009**

and is/are identical to the PPE which is/are the subject of type-examination (Module B of Regulation 2016/425 on personal protective equipment, as amended to apply in GB) referenced on the certificate number:

**UKCA 781390 (Issue Date: 24/01/2023)**

issued by

BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, UK, Approved Body No. 0086

and is/are subject to the procedures set out in Module D of the UK Personal Protective Equipment Regulation under the surveillance of BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, UK, Approved Body No. 0086

### **Medical Device Regulation**

The model is/are classified, per Part II of the UK Medical Device Regulation (MDR) 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002), as Class I Medical Devices and as such meet the relevant essential requirements, of Part II of the UK MDR 2002, Annex I (as modified by Part II of Schedule 2A to the UK MDR 2002), and with the Standard Number(s):

**EN 14683:2019+AC:2019**

Signed by: D. Kang

Date: 16<sup>th</sup> February 2023

Certification and Conformance Manager EMEA

Personal Safety Division  
3M United Kingdom PLC