



# DECLARATION of CONFORMITY

## EU Declaration of Conformity

**Manufacturer:** ISOFIELD SDN BHD No.6, Jalan Gudang 16/9, 40200, Shah Alam, Malaysia

**Authorized representative:** ISOFIELD (IRELAND) LIMITED 70 Northumberland Road, Ballsbridge, Dublin 4, Ireland

Declares under their sole responsibility that the PPE described below

**ISOFIELD STERILE 300MM NITRILE HAND SPECIFIC CLEANROOM GLOVES (Product Code: 20050/20530)**

### PPE RISK CATEGORY III

is in conformity with the provision of Regulation (EU) 2016/425 and with the European Harmonized standards EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016 and is subject to the procedure set out in Annex V (Module B) of the regulation under certificate number 2777/22161-01/E00-00 , issued by the Notified Body SATRA Technology Europe (2777), Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland and conformity assessment procedure (module D) under surveillance of the Notified Body BSI Group The Netherlands B.V.(2797), Say Building, John M.Keynesplein 9, 1066 EP Amsterdam, Netherlands

ISOFIELD SDN. BHD.  
(Registration No: 201501038008 (1348338-A))

  
Authorized Signatory



Stephen Morgan  
Managing Director  
Date : 19.08.22



# DECLARATION of CONFORMITY

## UK Declaration of Conformity

**Manufacturer:** ISOFIELD SDN BHD No.6, Jalan Gudang 16/9, 40200, Shah Alam, Malaysia

**Authorized representative:** ISOFIELD LTD, Hyperion House, The oaks, Fordham Road, Newmarket, Suffolk, CB8 7XN, United Kingdom

Declares under their sole responsibility that the PPE described below

**ISOFIELD STERILE 300MM NITRILE HAND SPECIFIC CLEANROOM GLOVES (Product Code: 20030/20530)**

### PPE RISK CATEGORY III

is in conformity with the provision of Regulation 2016/425 on personal protective equipment, as amended to apply in GB and with the European Harmonized standards EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016 and is subject to the procedure set out in Annex V (Module B) of the regulation under certificate number AB0321/22954-01/E00-00 , issued by the Approved Body SATRA Technology Centre Ltd (0321), Wyndham Way, Kettering NN16 8SD, United Kingdom and conformity assessment procedure (module D) under surveillance of the Approved Body BSI Assurance UK Ltd (0086), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.



Stephen Morgan  
Managing Director  
Date: 28/11/2022