



**Alliance Rubber Products Sdn. Bhd.** (52446-U)

Lot 2716 & 2720, Mk 7, Kawasan Perindustrian Bukit Panchor, 14300 Nibong Tebal, Pulau Pinang, Malaysia.  
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Your Ref :

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## DECLARATION OF CONFORMITY

We, Alliance Rubber Products Sdn. Bhd. and address Lot 2716 & 2720 MK 7, Kawasan Perindustrian Bukit Panchor, 14300 Nibong Tebal, Pulau Pinang, Malaysia hereby declare under our sole responsibility that the product(s) listed in Annex comply(ies) with the provisions of the Medical Device Regulations 2002 (SI 2002 n. 618) (UK MDR 2002) as amended by Medical Device regulations (Amendment etc.) (EU Exit) Regulations 2020 (MDRs 2020).

The Manufacturer has designed the following authorized representative within the UK:

Obelis UK Ltd.  
Sandford Gate  
Oxford  
OX4 6LB  
United Kingdom  
Phone: +44.1491.378012  
E-mail: [info@obelis.co.uk](mailto:info@obelis.co.uk)

The devices are Class 1 following Rule 1 of Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002)

The following conformity procedure(s) has (have) been applied in order to affix the UKCA marking on the device( s) :

Class 1: the procedure referred to in Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002)

The SGS has issued the following certificate: Annex stated on the certificate ISO13485:2016 (EN ISO 13485:2016), reference : MY00/52111, issue date 22 July 2021.

This Declaration is valid for all products bearing the UKCA marking placed on the UK Market et as of the date of signature of this Declaration.

Pulau Pinang, Malaysia, 29<sup>th</sup> November 2021

Issue place and date

Chua Hooi Koon

Managing Director



Products are PPE approved  
under Regulation (EU)  
2016/425 Module D



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