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

Lot 2716 & 2720, Mk 7, Kawasan Perindustrian Bukit Panchor, 14300 Nibong Tebal, Pulau Pinang, Malaysia.
Tel: 604-593 2235, 593 7616 Fax: 604-593 2262 E-mail: alliancerubber@alliancerubber.com

Your Ref : Our Ref : Date : Page :

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

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 19 July 2018.

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, 28th July 2021

Issue place and date

Chua Hooi Koon

Managing Director

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

UK	RP
Obelis UK Ltd. Sandford Gate East Point Business Park Oxford OX4 6LB United Kingdom Tel:+44.1865.910.145 Email:info@obelis.co.uk	