



## **UK Declaration of Conformity**

## for

## **Class I Medical Devices**

Manufacturer:

Sharon Services (UK) Limited Unit 69, Carntyne Industrial Estate Camelon Street Glasgow G32 6AF United Kingdom

I, the undersigned, hereby declare that the Class I medical devices specified below, conform to the applicable requirements described in Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002)

Product Code	Description
MK-OX-10KD	Procedure Type IIR Kids Mask with Ear Loops (Pack of 10)
MK-OX-10RL	Procedure Type IIR Blue Face Mask with Ear Loops - Polypack of 10
MK-OX-50BL	Procedure Type II Blue Face Mask with Ear Loops (Pack of 50)
MK-OX-50MM	Procedure Type IIR Metal Free Face Mask with Ear Loops (Pack of 50)
MK-OX-50PK	Procedure Type IIR Pink Face Mask with Ear Loops (Pack of 50)
MK-OX-50DU	Procedure Type IIR Black Face Mask with Ear Loops (Pack of 50)
MK-OX-50RL	Procedure Type IIR Blue Face Masks with Ear Loops (Pack of 50)
MK-OX-50TB	Procedure Type IIR Blue Face Masks with Tie Backs (Pack of 50)

## Standards Applied:

BS EN 1041:2008 / A1:2013, ISO 15223-1: 2016, EN 14683:2009+AC:2019, ISO 22609:2004 & ISO 9001:2015

This declaration is made under UK Medical Device Regulation 2002 in conjunction with registration by the manufacturer with the UK Competent Authority. Under our sole responsibility the products to which this declaration relates are in conformity with the safety and performance requirements of the above Regulation.

Signed:

Sharon D'souza Managing Director

Sharon Services (UK) Limited

Date: 12.05.2021

MK-OX-UKDOCv1