



SHARON SERVICES

EC Declaration of Conformity
for
Class I Medical Devices

Manufacturer:

Sharon Services (UK) Limited
Units 3 & 4, Block 20
88 Clydesmill Place
Clydesmill Industrial Estate
Glasgow
G32 8RF
United Kingdom

EC Rep:

Sharon Services Europe B.V.
Industrieweg 19-B
1586 JN Assendelft
Netherlands

I, the undersigned, hereby declare that the Class I medical devices specified below conform to the applicable requirements listed in EC Directive 93/42/EEC, as amended by Medical Device Regulation 2017/745/EU.

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: 2018, EN 14683:2009+AC:2019, ISO 22609:2004 & ISO 9001:2015

This declaration is made under Annex I of Medical Device Regulation 2017/745/EU in conjunction with registration by the manufacturer with the Competent Authority. Under our sole responsibility the products to which this declaration relates are in conformity with the safety and performance requirements of Annex I of the above Regulation.

Signed:
Sharon D'souza
Managing Director
Sharon Services (UK) Limited

Date: 01.12.2021

MK-OX-DOC4