

EC - DECLARATION OF CONFORMITY

In compliance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

FACEMASKS EARLOOP, LATEX - FREE

Page 1 of 1

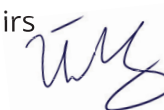
REF	PRODUCT DESCRIPTION		C = MP Class R = Rule	UMDNS
8400	Blue	The disposable, earloop face masks are intended to protect both the wearer and the patient from contamination caused by microorganisms through the drops and blood splashes, saliva, or wastewater, and when dealing with contaminated instruments.	CI - R1	12458
8500	Violet-blue			
8502	Lilac			
8600	Green			
8700	Pink			
8800	White			

Harmonised standards and normative documents: EN 14683:2014, TYPE IIR (BFE \geq 98%, splash resistant)

We hereby declare that the above mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations by bearing CE-marking.

Version: 3
Date: June 2019
Valid until: May 2024

Department: Regulatory Affairs
Name: Yordan Marinov
Signature:



Headquarters:

Comforties.com LTD
Parizhka Komuna 26
9000 Varna, Bulgaria

E info@comforties.com
W www.comforties.com