

EC - DECLARATION OF CONFORMITY

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

SOFT NITRILE BLUE, LATEX - FREE, POWDER - FREE

Page 1 of 1

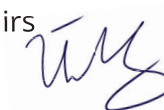
REF		PRODUCT DESCRIPTION	C = MP Class R = Rule	UMDNS	Personal protection Cat.	Notified Body
8000SB	S	Medical gloves for single use, intended to protect both the wearer and the patient from cross-contamination caused by microorganisms.	CI - R1, R5	11882	III	CE
8100SB	M					
8200SB	L					
8300SB	XL					

Harmonised standards and normative documents: EN 455 - 1, 2, 3, 4, EN 374 - 1, 2, 4, 5, EN 16523 - 1, EN 420 + A1 and EN 2016/425

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: May 2020
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