EC - DECLARATION OF CONFORMITY

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

SOFT NITRILE BASIC GLOVES, LATEX - FREE, POWDER - FREE

Page 1 of 1

BLUE	WHITE	PRODUCT DESCRIPTION		C = MP Class R = Rule	UMDNS	Personal protection Cat.
7900B	7900BW	XS	Medical gloves for single use, intended to protect both the wearer and the patient from cross- contamination caused by microorganisms.	CI - R1, R5	11882	I
8000B	8000BW	S				
8100B	8100BW	М				
8200B	8200BW	L				
8300B	8300BW	XL				

Harmonised standards and normative documents: EN 455 1, 2, 3, EN 374 1, 2, EN 16523 - 1 and EN 420 + A1

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

Headquarters:

Comforties.com LTD Parizhka Komuna 26 9000 Varna, Bulgaria

E info@comforties.comW www.comforties.com

Department: Regulatory Affairs Name: Yordan Marinov Signature: