

EC - DECLARATION OF CONFORMITY

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

NITRILIES BASIC Soft nitrile basic gloves (latex and powder free)

Page 1 of 1

S	M	L	XL	PRODUCT DESCRIPTION		C = MP Class R = Rule	UMDNS	Personal protection Cat.
2021-S	2022-M	2023-L	2024-XL	Blue	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
2021W-S	2022W-M	2023W-L	2024W-XL	White				

Harmonised standards and normative documents:

EN 455 1, 2, 3, EN 374 1, 2, 3 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

Department: Regulatory Affairs
Name: Yordan Marinov
Signature:



Headquarters:

Dutchblue.com Ltd.
Lyuben Karavelov Str. 6
9002 Varna

E info@dutchblue.com
W www.dutchblue.com

dutchblue.com