EC - DECLARATION OF CONFORMITY

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

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

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VIOLET- BLUE	WHITE	GREEN	PINK	PRODUCT DESCRIPTION		C = MP Class R = Rule	UMDNS	Personal protection Cat.	Notified Body
7900	7900W	7900G	7900P	XS	Medical gloves for single use, intended to protect both the wearer and the patient from crosscontamination caused by microorganisms.	CI - R1, R5	11882	III	CE
8000	8000W	8000G	8000P	S					
8100	8100W	8100G	8100P	М					
8200	8200W	8200G	8200P	L					
8300	8300W	8300G	8300P	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: June 2019 Valid until: May 2024 Department: Regulatory Affairs

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