

EC-DECLARATION OF CONFORMITY

In compliance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Council Directive 89/686/EEG/EC of 21 December 1989 concerning Personal Protective equipment.

COMFORTIES SOFT NITRIL PREMIUM EXAMINATION GLOVES, LATEX-FREE, POWDER-FREE

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REF	XS	S	M	L	XL	Intended use	Medical device		Personal protection	
							K = MP Class R = Rule	UMDNS	Cat.	Notified Body Satra / UK
Violet-blue	7900	8000	8100	8200	8300	Medical gloves for single use, intended to protect both the wearer and the patient from cross-contamination caused by micro-organisms.	K1-R5	11-882	III	CE 0321
White	7900W	8000W	8100W	8200W	8300W		K1-R5	11-882	III	CE 0321
Pink	7900P	8000P	8100P	8200P	8300P		K1-R5	11-882	III	CE 0321
Green	7900G	8000G	8100G	8200G	8300G		K1-R5	11-882	III	CE 0321

Harmonised standards: COMMISSION REGULATION (EU) No. 10/2011 of 14th of January, 2011 on plastic materials and articles intended to come into contact with food:

EN 455 1, 2, 3,4
EN 374 1, 2, 3 en EN 420 + A1

The Comforties soft nitril Basic examination gloves comply with the requirements of this Regulation and they are suitable for use during treatment of food.

We, as manufacturer, declare under our sole responsibility that the above mentioned examination gloves comply with the Class 1 medical devices directive and the directive on personal protective equipment of IIIrd category and respectively bear the CE-marking.

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