



EC DECLARATION OF CONFORMITY

Manufacturer: SANTEX 2000 Internacional SL; Paseo de la castellana 141, plantas 18 y 19, Cuzco IV 28046-MADRID (ESPAÑA)

Declares that the product:

POWDER-FREE NITRILE EXAMINATION GLOVES

Sizes: XS / S / M / L / XL

Product code: GD19, GD20, GD21, GD22, GD23, GD30
(Please check the Anex I for more details)

The product covered by this declaration complies with the Medical Devices Regulation (EU) 2017/745, as well as the requirements established in the following standards: EN ISO 13485:2016, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009.

According to the rules set out in Annex V, Chapter III of Regulation (EU) 2017/745, it is a Class I Medical Device, with UMDNS code 11882, and Basic UDI-DI: 84370NITRILOTV.

Consequently, it bears the marking 

Intended use: The product is a single-use device designed for medical applications, to be worn on the healthcare professional's hand in order to prevent the transmission of contaminants between the patient and the examiner.

Signed in Madrid on behalf of SANTEX 2000 Internacional SL:

A handwritten signature in blue ink, appearing to read "Stefan Vintu", with a large, sweeping flourish extending from the end.

Stefan Vintu
Quality and RA Manager

Date: 04/02/2026



ANEX I

COLOR	SIZES				
	XS	S	M	L	XL
BLUE	GD19BA	GD19BB	GD19BC	GD19BD	GD19BE
	GD20BA	GD20BB	GD20BC	GD20BD	GD20BE
		GD21BB	GD21BC	GD21BD	GD21BE
		GD22BB	GD22BC	GD22BD	GD22BE
		GD30BB	GD30BC	GD30BD	GD30BE
BLACK	GD19NA	GD19NB	GD19NC	GD19ND	GD19NE
	GD20NA	GD20NB	GD20NC	GD20ND	GD20NE
		GD21NB	GD21NC	GD21ND	GD21NE
		GD23BB	GD23BC	GD23BD	GD23BE
WHITE	GD20WA	GD20WB	GD20WC	GD20WD	GD20WE
MAGENTA	GD20MA	GD20MB	GD20MC	GD20MD	GD20ME
PINK	GD20RA	GD20RB	GD20RC	GD20RD	GD20RE
PURPLE	GD20PA	GD20PB	GD20PC	GD20PD	GD20PE
COBALT BLUE	GD20CA	GD20CB	GD20CC	GD20CD	GD20CE
GREEN	GD20GA	GD20GB	GD20GC	GD20GD	GD20GE