



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 BLACK LATEX EXAMINATION GLOVES

Sizes: XS / S / M / L / XL

Product code: GD06N

(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, stylized flourish extending from the end.

Stefan Vintu
Quality and RA Manager

Date: 04/02/2026



ANEX I

COLOR	SIZES				
	XS	S	M	L	XL
BLACK	GD06NA	GD06NB	GD06NC	GD06ND	GD06NE

Date: 04/02/2026