



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 VINYL EXAMINATION GLOVES

Sizes: S / M / L / XL

Product code: GD10, GD14

(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			
	S	M	L	XL
TRANSPARENT	GD10NB	GD10NC	GD10ND	GD10NE
BLUE	GD14BB	GD14BC	GD14BD	GD14BE