



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 DIAMOND NITRILE EXAMINATION GLOVES

Sizes: M / L / XL / XXL

Product code: GD26

(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 **CE**

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", written over a faint, light blue rectangular stamp.

Stefan Vintu
Quality and RA Manager

Date: 04/02/2026



ANEX I

COLOR	SIZES			
	M	L	XL	XXL
ORANGE	GD26OC	GD26OD	GD26OE	GD26OF
BLACK	GD26NC	GD26ND	GD26NE	GD26NF

Date: 04/02/2026