



DECLARATION OF CONFORMITY

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

Declares that the product:

POLYPROPYLENE GOWN

Sizes: M, L, XL, XXL

Product code: DC02, DC03, DC04, DC06, DC07

(Please refer to Annex I for further details)

Complies with Regulation (EU) 2017/745 on Medical Devices. This product provides protection and may be used in healthcare settings by healthcare professionals and patients. It is a non-sterile, single-use product. During the processing and manufacture of this product, all applicable health regulations are complied with. The manufacturing facilities where the product is manufactured are certified in accordance with the harmonized international standard ISO 13485:2016.

Signed on behalf of SANTEX 2000 Internacional SL:

A handwritten signature in blue ink, consisting of several vertical strokes followed by a diagonal line crossing them.

Quality and Regulatory Affairs Manager

Date: 24/07/2026

Version No.: 01



ANNEX I

COLOR	REFERENCES and SIZES				
WHITE	DC02WC DC02WD DC02WE DC02WF	DC03WE	DC04WE	DC06WE	
BLUE	DC02BC DC02BD DC02BE DC02BF	DC03BE	DC04BE	DC06BE	
GREEN	DC02GC DC02GD DC02GE DC02GF		DC04GE		DC07GC
RED	DC02RC DC02RD DC02RE DC02RF		DC04RE		