



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:

POLYETHYLENE OVERSLEEVES

One size

Product code: DA01, DA02, DA03

(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		
WHITE	DA01WC	DA02WC	DA03WC
BLUE	DA01BC	DA02BC	DA03BC
GREEN	DA01GC	DA02GC	DA03GC
RED	DA01RC	DA02RC	DA03RC