



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:

DISPOSABLE POLYETHYLENE SHOE COVERS

One size

Product code: DF01, DF02, DF03, DF04

(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	DF01WB	DF02B5		DF04TB
BLUE	DF01BB		DF03BB	DF04BB
GREEN	DF01GB			
RED	DF01RB			