EC DECLARATION OF CONFORMITY

Product: SX01 POWDERED LATEX EXAMINATION GLOVES

SANTEX 2000 INTERNACIONAL SL in Paseo de la Castellana, 141 plantas 8 y 9, Cuzco IV 28046 Madrid, with SRN: ES-MF-000026359 declares that:

This declaration of conformity is issued under the sole responsibility of the manufacturer.

The afore mentioned materials and products have been revised in accordance with the self-declaration of conformity requirements for EC marking according to the Medical Devices Regulation (EU) 2017/745, and standards EN 455-1, EN 455-2, EN 455-3.

In the transformation and production of the film, all current health standards are followed, being the facilities where it has been manufactured certified with the international harmonized standard ISO 13485: 2016.

According annex VIII Regulation (EU) 2017/745, It is a class I medical device and Basic UDI-DI: 84370LATEXUT.

In Mataró, on July 25, 2022

Responsible de QA/RA