

EC Declaration of Conformity

Product: Latex Examination Gloves non-sterile
Product model/size: XL, L, M, S
Manufacturer: Hebei Sanxing Medical Latex Products Co., Ltd. Dabu Industrial Zone of Xiong County, Baoding, Hebei, 071800, China
Base Polymer: Natural Rubber Latex
Product Standards: EN 455-1:2000, EN 455-2:2015, EN 455-3:2016, EN 455-4:2009

We the manufacturers hereby declare that the above mentioned product complies with the European Medical Device Directive 93/42/EEC and is in accordance with Annex V of the EEC Directive, supported by the Conformity Assessment Procedure and adhering to the essential requirements in accordance with Annex IX of the European Medical Device Directive 93/42/EEC for class I devices.

This self-declaration is made on the basis of the Certificate No SX601289160001 issued by TUV Rheinland LGA Products GmbH -Tillystrabe 2, 90431 Nurnberg, Germany (notified body no 0197) establishing the above mention manufacturer applies a quality management system for medical devices required under specified standard EN ISO 13485:2016

CE marking is carried out as per Annex V of the European Medical Devices production quality assurance 93/42/EEC.

Storage Instruction: Store between 5°C and 25°C in a cool dry environment away from direct sunlight.

User Information: Gloves cannot be cleaned and reused. Before use, check gloves for physical damage. Do not use damaged gloves.

Fitting and sizing: Only wear products of a suitable size. Products which are either too loose or tight will restrict movement and will not provide the optimum level of protection.

Allergy advice: This product contains natural rubber latex and may contain low levels of residual chemical accelerators, which may cause allergic reactions.

This declaration is valid for the above product in its original, unmodified, unopened and undamaged condition.

Sign/Stamp:

Dated: 2020.8.3
General Manager: Zhang Na
Hebei Sanxing Medical Latex Products Co, Ltd
Dabu Industrial Zone of Xiong County,
Baoding, Hebei, 071800, China

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