



SARL TOP GLOVES LATEX INDUSTRIES
UNITE DE FABRICATION DES GANTS A USAGE MEDICAL ET CHIRURGICAL
N°288, Zone Industrielle, Ain Témouchent - Algérie
Boite Postale : 656 RP
Tél/Fax : 043 78 09 48 - E-mail : topgloves@yahoo.com

CE declaration of conformity

According to Annex VII of Directive 93/42 / EEC relating to medical devices

We,

SARL TOP GLOVES LATEX INDUSTRIES
168, RUE NACHAT ABDELKADER MARAVAL ORAN ALGERIA



Guarantee and declare, under our sole responsibility, that the following medical devices:

- **Non-Sterile Latex Exam Glove**
- **Non-Sterile Nitrile Exam Glove**

Class I, in application of Rule 1: All non-invasive devices are in Class I, unless one of the following rules applies, of Annex IX to European Directive 93/42 / EEC , comply with the applicable requirements of Council Directive 93/42 / EEC of June 14, 1993 relating to medical devices.

Manufacturer : SARL TOP GLOVES LATEX INDUSTRIES
Headquarters : 168, Rue Nachat Abdelkader Maraval Oran Algeria
Manufacturing Place : 288, Zone Industrielle Ain Témouchent Algérie
Agent established within
From the European community: CONFORT MEDICAL GLOVES, SL
ALVAREZ SEREIX, 11, ENT DCHA
03001 Alacant/ Alicante SPAIN
Device Class : Class I
Application rule : Rule 1, According to annex IX of the European directive
Council 93/42 / EEC of June 14, 1993



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Applied standards : :

ISO 9001 : 2015	Quality management systems — Requirements
ISO 13485 : 2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN 455-1	Medical gloves for single use. Requirements and testing for freedom from holes
EN 455-2	Medical gloves for single use. Requirements and testing for physical properties
EN 455-3	Medical gloves for single use. Requirements and testing for biological evaluation
EN 455-4	Medical gloves for single use. Requirements and testing for shelf life determination
ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

Signature Autorisée :

