

EC-DECLARATION OF CONFORMITY

Product: **LATEX GLOVES**
non sterile, powder-free
Class I

We declare that the above mentioned product satisfies the requirements laid down in MDD 93/42/EEC, as amended by the Council directive 2007/47/EC.

Requirements of the EN 455 parts 1, 2, 3, 4:

- Water tightness test: gloves shall not leak when tested in accordance with clause 5. Sample size and allowable number on non-conforming gloves in accordance with ISO 2859-1, general inspection level I, AQL 1.5
- Tests were performed on gloves to ensure an acceptable performance of the products (physical and biological tests).
- The product passed all quality inspection methods in accordance with shelf life determination requirements.

The gloves are manufactured according to ISA 13485:2003 and EN ISO 13485:2012 Quality Management Systems and are certified by TUV SUD America Inc. 10 Centennial Drive Peabody, MA 01960 USA.

Akzenta International SA

Chiasso, 01.01.2018

Signature and stamp:

Printed name:
Position:

Luciana Piacquadio
Head of office

