

REFLEXX S.p.A. Unipersonale DECLARATION OF CONFORMITY rev. 02 del 11 dicembre 2018

Product: reflexx 51 art. R51/ XS - art. R51/ S - art. R51/ M - art. R51/ L- art. R51/ XL

Emessa da G.Isetti – Amm.re Unico Pag.: 1/1

## DISPOSABLE NON-STERILE EXAMINATION LATEX GLOVES TRADEMARK REFLEXX 51

The company REFLEXX SpA, located in Via Passeri, 2 in Viadana (MN) as Manufacturer declares that the product meets the requirements of the following European Community Directives:

- □ As a PPE category I risk according to Reg.EU 2016/425. The product is certified according to the EN 420 and EN 374.
- □ As Medical Device Class I fall in between devices by invasive examination also intended for temporary use in accordance with Directive 93/42/EEC and subsequent Legislative Decree 37/2010 on the implementation Dir 2007/47/EEC. The product is in accordance with the EN 455 1-2 and 3. CND T010201 LATEX GLOVES mis. XS/1522253 S/1524280 M/1526319 L/1526320 XL/1526321

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