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REFLEXX S.p.A.

DECLARATION OF CONFORMITY CE rev 07 del 20 dicembre 2017

Product: reflexx 46 art. R46/ XS - art. R46/ S – art. R46/ M – art. R46/ L– art. R46/ XL

Emessa da G.Isetti - Amm.re Unico

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DISPOSABLE LATEX GLOVES TRADEMARK REFLEXX 46

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 III risk according to IT Legislative Decree 475/92 implementing Dir 89/686/EEC (CIMAC, authorized Ministerial: 0465). The product is certified according to the EN 420:2003 + A1 2009, EN 374-1:2016 TYPE B, EN 374-2:2015, EN 374-4:2013 e EN 374-5:2016.

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/1564822 S/1564823 M/ 1564824 L/1564825 XL/1564826

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