



**REFLEXX S.p.A. Unipersonale**

**DECLARATION OF CONFORMITY**

**rev 05 del 23 novembre 2018**

Product: reflexx 78 - art. R78/XS- art. R78/S- art. R78/M- art. R78/L- art. R78/XL

*Emessa da G.Isetti – Amm.re Unico*

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## **DISPOSABLE EXAMINATION NITRILE GLOVES TRADEMARK REFLEXX 78**

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 Reg UE 2016/425 (ANCI\_CIMAC, corso Brodolini, 19 27029 Vigevano (PV): Authorized Ministerial Body n. 0465). The product is certified according to the EN ISO 374-1:2016 TYPE B and EN ISO 374-5:2016

-As a medical device, it falls into Class I as an invasive device for temporary use in accordance with Directive 93/42/EEC and subsequent Legislative Decree 37/2010 in implementation Dir 2007/47/CEE. The product complies with the EN 455 1-2-3 and 4. CND T01020204 - NON-SURGICAL GLOVES IN NITRILE. System Progressive number Attributed to the DM: **mis. XS/1564830 S/1543992 M/1543993 L/1543994 XL/1543995**

In fede

**REFLEXX S.p.A.**

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