Date: January 8, 2021

Declaration of Conformity

To: **Medline International B.V.**

WHEREAS

We 3.M.C. S.p.A, who are official manufacturers of disposable medical gowns, residing at 70132 Bari (BA) Italy, Viale Francesco De Blasio, 15 - Z.I.,

- D/1006 Protex Disposable Nonwoven Isolation Gown

DECLARES

under his own responsibility that the devices referred to in the object satisfy all the applicable provisions contained in the EEC Directive 93/42 on Medical Devices.

- the devices in question belong to class I according to rule 1 of paragraph III of Annex IX
- the products in question meet all the applicable essential requirements required by Annex I of Directive 93/42 / EEC on medical devices;
- the devices in question are sold in NON STERILE packaging;
- the devices in question are not a measuring instrument;
- the devices in question are not intended for clinical investigations;
- the manufacturer undertakes to preserve and make available to the national authorities the technical documentation specified in Annex VII of the EEC Directive 93/42 for a period of 5 years from the date of last manufacture of the product.

It is therefore declared that the devices in question comply with the provisions of the EEC Directive 93/42(Directive 47/2007/CEE) and that they are placed on the market with the CE marking, according to the provisions of Article 16 of the EEC Directive 93/42.

Yours Sincerely,

3.M.C. S.p.A.
70132 - Zona Ind.le - BARI