CONFORMITY DECLARATION

European Directive 93/42/EEC, *transponed in Italy with D.Lgs. N°46 of 1997,* amended by European Directive 2007/47/EC;

Hereby **NEX MEDICAL ANTISEPTICS S.R.L.**, manufacturer of the Medical Device with commercial name:

NEX IODIO P2

DECLARES AND GUARANTEES WHAT FOLLOWS:

1. The product described meets all the requirements of the European Directive 93/42/EEC amended by the European Directive 2007/47/EC.

2. The product described meets all the essential requirements requested by Annex I of the European Directive 93/42/EEC transponed in Italy with D.Lgs. N°46 of 1997 and subsequent amendments (European Directive 2007/47/EC).

3. The product is a Medical Device belongs to the **Class I** according to Rule No. 1 of Annex IX of the European Directive 93/42/EEC in compliance with Annex VII of European Directive 93/42/EEC amended by European Directive 2007/47/EC;

4. The product does not have measuring functions, does not contain medicines or products derived from blood, does not contain human or animal tissue or phthalates or latex;

5. The manufacturer is committed to preserve and make available for Health Authority product documentation (Technical Dossier and Production Reports) for a minimum period of ten (10) years from the date of manufacturing;

CHRISTOPHER HILL
(Responsible Person)

NEX MEDICALANTISEPTICS SRL
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Casorezzo 06/02/2024

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