

CONFORMITY DECLARATION

of the Medical Device

NEX D1 DRY

Manufactured by NEX MEDICAL ANTISEPTICS S.R.L. according to the essential requirements in Annex I of the European Directive 93/42/EEC and subsequent amendments.

Hereby **NEX MEDICAL ANTISEPTICS S.R.L.**, in the person of the *Legal Representative Silvio Daneluzzi*, manufacturer of the Medical Device with commercial name "**NEX D1 DRY**", declares and guarantees, under its own responsibility, what follows:

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

According to this, NEX MEDICAL ANTISEPTICS S.R.L. guarantees and declares what follows:

1. EC Certificate has been released and issued by *Notify Body N° 0476 KIWA CERMET ITALIA S.p.A. Via Cadriano, 23, 40057 Granarolo dell'Emilia BO* valid until 2024-05-26, which indicates the product compliance with European Directive 93/42/EEC amended by European Directive 2007/47/EC;
2. **NEX D1 DRY** is Medical Device belongs to the **Ila Class** according to Rule No. 6 of Annex IX of the European Directive 93/42/EEC in compliance with Annex II of European Directive 93/42/EEC amended by European Directive 2007/47/EC;
3. This Medical Device does not have measuring functions, does not contain medicines or products derived from blood, does not contain animal tissue or phthalates; this Medical device is steril.
4. The manufacturer is committed to preserve and make available to Notified Body all product documentation (Technical Dossier and Production Reports) for a minimum period of ten (10) years from the date of manufacturing;
5. The manufacturer has notified to Competent Authority, after the commissioning of the Medical Device in question on the market, the procedure of post-market surveillance of the product as required by European Directive 93/42/EEC amended by European Directive 2007/47/EC.

SILVIO DANELUZZI
(Legal Representative)



NEX MEDICAL ANTISEPTICS S.R.L.