

CONFORMITY DECLARATION

of the Medical Device

NEX D1 DRY

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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 sterile.
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

NEX MEDICAL ANTISEPTICS S.R.L.
via per Ariuno 37/39, Casorezzo (MI) - ITALY
Ph: +39 02 9029 7821 - www.nexmedical.com; info@nexmedical.com

NEX MEDICAL ANTISEPTICS SRL
Via per Ariuno, 37/39 - 20010 Casorezzo (MI)
tel. +39 02.90297821 - fax +39 02.90383137
Codice Fiscale e Partita IVA 08553480964
Cap Soc. Euro 20,000 i.v.

Casorezzo, 02/12/2020