



## DECLARATION OF CONFORMITY n. 04/19

We undersigned ERBAGIL S.R.L, with head office addressed in Telese Terme (BN), Via Luigi Settembrini 13, cap 82037, declare under its own responsibility that the medical device “**OTORIG - Drops**”, risk class I (non sterile), according to rule 5 to the Directive 93/42/EEC and further amendments, Annex IX (enforced in Italy by Legislative Decree No. 46/1997 and further amendments), as amended by the Directive 2007/47/EC (enforced in Italy by Legislative Decree No. 37/10):

- is complied with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as the Technical File no. FT 004 ER retained by the Company;
- is manufactured according to the Quality System which satisfies requirements of Annex VII of the above mentioned Legislative Decree

Legal Representative

**ERBAGIL s.r.l.**

Via L. Settembrini, 13  
82037 TELESE TERME (BN)  
P.IVA-C.F. 01468980626  
www.erbagil.com

Telese Terme (BN), 3<sup>rd</sup> January 2019

**ERBAGIL s.r.l.**

**Iscritta al registro imprese di Benevento**

**Codice Fiscale, Partita IVA e n. iscrizione al registro imprese: 01468980626**

**sede sociale: via L. Settembrini, 13 – 82037 Telese Terme (BN) – Italy**

**R.E.A. n.122907 – capitale sociale: € 10.000,00 interamente versati**

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