



## DECLARATION OF CONFORMITY n. 15/21

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 devices

RIGENOMA ® CREMA  
RIGENOMA ® CREAM  
RIGENOMA ® KREMA  
RIGENOMA ® MAX CREAM  
RIGENOMA ® KPEMA  
RIGENOMA ® KREM  
PODOPED ® CREMA  
PODOPED ® CREAM  
ACNOZOIL ® CREMA  
ACNOZOIL ® CREAM  
DERMOZOIL ® CREMA  
DERMOZOIL ® CREAM  
DERMAZOIL ® CREMA  
PSOZOIL ® CREMA  
PSOZOIL ® CREAM  
РИГЕНОМА® КРЕМ  
РИГЕНОМА® МАКС КРЕМ  
RIGENOMA ® SPRAY  
RIGENOMA ® SPREJ  
RIGENOMA ® PRŠILO  
PODOPED ® SPRAY  
DERMAZOIL ® SPRAY  
РИГЕНОМА® СПРЕЙ

- risk class IIb, according to rule 4 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):

- are compliant with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as the Technical File no. FT 009 ER retained by the Company;

are manufactured according to the Quality System which satisfies requirements of Annex II (excluding point 4) of the above mentioned Legislative Decree, as for CE Certificate no. 0425-MED-003690-00, released on 31/07/2019 by ICIM S.p.a., Notified Body no. 0425, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI).

Telese Terme (BN), 24/05/2021

Legal Representative

**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**

**Tel.: +39 0824.865004 – Fax: +39 0824.975740**

**e-mail: info@erbagil.com - website: www.erbagil.com - PEC: erbagil@pec.it**

**ERBAGIL s.r.l.**

Via L. Settembrini, 13

82037 TELESE TERME (BN)

P.IVA-G.F. 01468980626

www.erbagil.com