



DECLARATION OF CONFORMITY n. 09/17

We undersigned ERBAGIL S.R.L, with head office addressed in Telesse Terme (BN), Via Luigi Settembrini 13, cap 82037, declare under its own responsibility that the medical device “**PROCTEN - Cream**”, 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.8 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



Telesse Terme (BN), 3rd January 2017

ERBAGIL s.r.l.

Iscritta al registro imprese di Benevento

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

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