

DECLARATION OF CONFORMITY

I, Luigi Mercuri, CEO of D.M.G. ITALIA SRL, a corporation duly organized and existing under the laws of Italy, with its Head Office in via Laurentina Km. 26.700 – 00071 Pomezia, Rome - Italy, registered at n° 773371 in the “Directory of Enterprises” of the Chamber of Commerce of Rome”, hereby

DECLARE

that our product:

“Unguento Barriera Emostatico (*Haemostatic Barrier Ointment*)”

a Medical Device class III,

- is in compliance with the essential requirements of Annex I of Council Directive 93/42/EEC of 14 June 1993;
- is manufactured according to Annex II excluding (4) of Council Directive 93/42/EEC and subsequent modifications and integrations;
- was notified with the commercial name of **Emofix**.

With this aim, I am enclosing the copy of the following documents:

- **EC Design -Examination Certificate - Document n° EPG-122-18**, issued on 25.06.2018 by Istituto Superiore di Sanità, Notified Body n. 0373, and
- **EC Declaration of Conformity Full Quality Assurance System – Document n° QCT 0090-18/05-18**, issued on 25.06.2018 by Istituto Superiore di Sanità, Notified Body n. 0373.

D.M.G. Italia srl



Luigi Mercuri
Amministratore Unico/CEO

D.M.G. ITALIA S.r.l.
Via Laurentina Km. 26,700
00071 POMEZIA (RM)
P. IVA/C.F. 04502861000

Pomezia, Rome (Italy), 13/05/2021

Encl: 2