



**protechno**

## EC-DECLARATION OF CONFORMITY

MANUFACTURER: FAMADENT, S.L.U.  
c/ Garrotxa, 6 – Vilamalla ( 17469 ) Girona , Spain

MANUFACTURER LICENCE NUMBER: 7449-PS

PRODUCT: **Oral Bio Filter OBF**

CODES: OBF-006, OBF-040

CLASSIFICATION: Class I, rule 5 according to Annex IX of the MDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED: EN ISO 13485 :2016, EN ISO 14971:2012, EN ISO 15223-1:2016

START OF CE-MARKING: 19/09/2019

PLACE, DATE OF ISSUE: Vilamalla, 19<sup>th</sup> September 2019

SIGNATURE:

*Miguel Naval, Manager Director*