EC DECLARATION OF CONFORMITY

Directive 93/42/EEC

The undersigned Company

Labomar S.p.A. a socio unico, via N. Sauro 35 I, Istrana (TV), Italy

Legal Manufacturer of the Medical Device

Device name:	**JALOSOME ORAL BARRIER**
REF:	**FTP82**
Destination of use:	**Medical Device indicated for the management of the painful symptoms of the mucositis of the oropharyngeal cavity.**
Risk Class:	**IIb**
Rule (Annex IX):	**V**
NBOG:	**MD0303**

Declares under its sole responsibility that the above mentioned Device complies with general safety and performance requirements of Annex I of Directive 93/42/EEC as amended by Directive 2007/47/EC.

Conformity assessment procedure:	**Annex II (excluded point 4)**
Notified body:	**Eurofins Product Testing Italy s.r.l** no. **0477**
CE certificate no.:	**EPT 0477.MDD.19/3533**
CE certificate expiry date:	**2024.31.01 (extended to 2028.31.12 according to EU Reg. 2023/607)**

Istrana (TV), Italy.
Date: February 012th, 2024

Luciano Marton
General Manager