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:	**SMILEUM**
REF:	**FTP91**
Destination of use:	**Medical device indicated for the treatment of irritable bowel syndrome, characterized by pain, swelling, stomachache, distension and abdominal discomfort, associated or not with variation in stools appearance and impaired intestinal transit (constipation, diarrhea or alternation of both).**
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.21/4365**
CE certificate expiry date:	**2024.01.31 (extended to 2027.12.31 according to EU Reg. 2023/607)**

Istrana (TV), Italy
Date: March 06th, 2024

Luciano Marton
General Manager