

Istrana, 2023 March 27th

OBJECT: Declaration on EU Reg. (EC) 2017/745 transition for Device REF FTP 82 “Jalosome Oral Barrier”

The undersigned company

Labomar SpA
Via Nazario Sauro 35/i
Istrana (TV)
IT-MF-000007965

Hereby declares under his sole responsibility that the Medical Device REF no. FTP82, “Jalosome Oral Barrier”:

- is covered by certificate no. 0477.MDD.19/3533, issued by notified body no. 0477 and valid until 2024.01.31;
- falls within the definition of medical device according to article 2 of EU Reg. 2017/745 (EU MDR) and is therefore intended for certification according to such Regulation.

The undersigned company has signed a written agreement with accredited notified body no. 0477 in accordance with Section 4.3, second subparagraph, of Annex VII to EU MDR for the conformity assessment of the device in subject, as a consequence it may be placed on the market until 31 December 2028, according to prescription stated on Reg. (EU) 2023/607.

Technical file submission to accredited notified body no. 0477 for conformity assessment to EU MDR is planned for July 2023.

In faith,



Davide Nenzioni,
Head of Regulatory and Medical Device Division Manager
Labomar S.p.A