

MANUFACTURER'S DECLARATION OF CONFORMITY

The company FlexiLigner srl, with headquarters in Guidonia, Via delle Genziane n. 13 E - 00012 Rome, VAT/C.F. 15139331001, hereby declares that:

The dental laboratory registered in the Register of Manufacturers of Custom Medical Devices with the Ministry of Health, no. ITCA01043198, has manufactured the mobile orthodontic appliance in compliance with the essential safety and quality requirements set out in Annexes I and VII of EU Regulation 2017/745 (MDR - Medical Device Regulation) using materials exclusively for custom-made Class IIa medical devices.

DECLARES

That the device in question is intended exclusively for use by the patient
[Patient's Name] _____

The device provided complies with the specifications outlined in the medical prescription of Dr. [Doctor's Name]_____

The above-mentioned patient has been informed that the required Declaration prepared by the manufacturer will be available to them for the next five years.

Date_____

Stamp and Signature