EU Declaration of Conformity

Manufacturer	ELI Innovation France S.A.S 73 route de Corbas 69200, Vénissieux
SRN	FR-MF-000035859
Product name	FREELI
Basic UDI-DI	3770040733FREELIZQ

ELI INNOVATION, hereby declares under its sole responsibility that the medical device identified as FREELI, a powered wheelchair intended to provide mobility assistance, complies with the requirements of Regulation (EU) 2017/745 on medical devices. The device is classified as a Class I medical device. FREELI is a non-invasive, active medical device intended to provide mobility assistance, and its classification has been determined in accordance with Annex VIII of Regulation (EU) 2017/745, applying the relevant rule(s) for active powered medical devices. The conformity assessment of the device is supported by performance and safety evaluations conducted in accordance with the ISO 7176 series of standards, as documented in the CERAH test report 23-065-A EN, including:

ISO 7176-1 relating to static stability,
ISO 7176-2 relating to dynamic stability,
ISO 7176-3 relating to braking performance,
ISO 7176-4 relating to energy consumption and range,
ISO 7176-6 relating to maximum speed,
ISO 7176-8 relating to static strength, impact and fatigue testing,
ISO 7176-10 relating to obstacle climbing and descending,
ISO 7176-22 relating to preparation and adjustment for testing.

This declaration is issued under the sole responsibility of the manufacturer.

Franck Marciano
Président