EU MDR Declaration of Conformity
Allora 3

Manufacturer	Jabbla bv Foreestelaan 3 B-9000 Gent Belgium
Represented by	Bart Noé Director
Device group	Alternative and Augmentative communication
Description	Keyboard input speech generating device for Augmentative and Alternative Communication (AAC)
Medical device classification	Class I
UDI-DI	543 0000 266 857 GS1
Product code	AL3 xxxx

Declaration of Conformity:

Jabbla bv declares under sole responsibility that the Allora 3 conforms to the relevant provisions of the Regulation EU MDR 2017/745 for medical devices, and is in accordance with the following harmonised standards:

EN 60601-2:2015	Home healthcare environment
EN 55032:2015	Radiated emission / Conducted emission
EN 61000-4-2:2009	Electrostatic discharge
EN 61000-4-3:2006	Radiated immunity
ISO 13485	Quality management for medical devices

Jabbla, Belgium, 5 October 2022

Bart Noé