

EU MDR Declaration of Conformity
Hey_

Manufacturer	Jabbla b.v. Foreestelaan 3 B-9000 Gent Belgium
Represented by	Bart Noé
Device group	Alternative and Augmentative communication
Description	Speech generating device accessory (2 nd display) for Augmentative and Alternative Communication (AAC)
Medical device classification	Class I
UDI-DI	543 0000 266 925 GS1
Product code /serial number	HE1 xxxx

Declaration of Conformity:

Jabbla b.v. declares under sole responsibility that the Hey_ 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, 17 May 2021



Bart Noé