EC Declaration of Conformity

EC Declaration of Conformity to Medical Devices Directive 93/42/EEC

Manufacturer	Jabbla b.v.b.a. Victoriastraat 52 B-9000 Gent Belgium
Represented by	Mr. Bart Noé Director
Device group	Alternative and Augmentative communication devices See attached device list of AAC devices.
Description	Dynamic display speech generating device for Augmentative and Alternative Communication (AAC)

Declaration of Conformity:

Jabbla b.v.b.a. declares that the AAC device Allora 2 conforms to the relevant provisions of the EC Council Directive 93/92/EEC dated 14 june 1993, Annex VII and is in accordance with the following harmonised standards:

EN 980:2008	Symbols for use in the labelling of medical devices
EN 5509:1998	User manuals, Contents, structure, formulation and presentation
EN 60601-1:2005	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN 60601-1-1:2000	Medical electrical equipment Part 1-1: General requirements for safety Collateral standard: Safety requirements for medical electrical systems
EN 60601-1-2:2007	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility. Requirements and tests

EN ISO 13485:2003	Medical devices Quality management systems Requirements for regulatory purposes
EN ISO 14971:2007	Medical devices Applications of risk management to medical devices

Jabbla agrees to develop, implement and maintain a document post-production Experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Jabbla, Belgium, May 2013

Bart Noé,
Director