



eQuality Time, 302 Cannon Hill Lane, London, SW20 9HN

Dear sir/madam,

*Request for confirmation of a software device*

eQuality Time has developed The Open Voice Factory. An open source website for communication. The Open Voice Factory is the first open-source option that is free at the point of delivery. <http://theopenvoicefactory.org/>.

The device is used by a person with speech difficulties. The user selects icons (or touches if the site is viewed on a touchscreen), and the page “speaks” a word or phrase to a listener, thus enabling the user to interact with other people.

With reference to the MHRA guidance “Medical device stand-alone software including apps (including IVDMDs)” (dated 25 August 2016):

- The device is standalone software, running on a computing platform, where content may be local to the device or sourced from the internet (page 6)
- Assuming that enabling a person with a disability to speak is considered to be a medical purpose (page 10 – the term “handicap” is replaced by “disability”).
- The Open Voice Factory is classified as a class I medical device by rule 12 (page 25, 26).

We hereby request confirmation as follows:

1. AzureJoe is a medical device
2. As a medical device, AzureJoe is classified as class I by rule 12.

Yours sincerely,

A handwritten signature in black ink, appearing to read "J Reddington", with a stylized flourish at the end.

Dr Joseph Reddington