

LI EC Declaration of Conformity



Legal Entity & manufacturing site	Jacoti bvba - Vlamingstraat 4 8560 Wevelgem, Belgium
Description of device concerned	Jacoti ListenApp
Software version	2.5
Variants	including bugfix revisions (2.5.x)
Conformity Assessment Route	Annex II of the Medical Devices Directive 93/42/EEC
Name & Address of Notified Body	BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP
Notified Body EC Code	0086
Regulatory Classification	Class IIa, according to Rule 9 of Annex IX of the Medical Devices Directive 93/42/EEC
Annex II certificate	CE 594667
Conformity End Date	June 2019

I, the undersigned, hereby declare that the Medical Device categories specified above and provided with the CE marking, meets the provisions of the EC Directive 93/42/EEC, including amendments issued in the years following which apply to them and I declare compliance with the relevant standards as detailed in the above mentioned table. Jacoti bvba is exclusively responsible for the declaration of conformity.

Place and date: Wevelgem, Belgium, 31 May, 2018.

Jacques Kinsbergen

Managing Director/CEO