

# HT EC Declaration of Conformity



<b>Legal Entity &amp; manufacturing site</b>	Jacoti bvba - Vlamingstraat 4 8560 Wevelgem, Belgium
<b>Description of device concerned</b>	Jacoti Hearing Center
<b>Software version</b>	1.3
<b>Variants</b>	including bugfix revisions (1.3.x)
<b>Conformity Assessment Route</b>	Annex II of the Medical Devices Directive 93/42/EEC
<b>Name &amp; Address of Notified Body</b>	BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP
<b>Notified Body EC Code</b>	0086
<b>Regulatory Classification</b>	Class IIa, according to Rule 10 of Annex IX of the Medical Devices Directive 93/42/EEC
<b>Annex II certificate</b>	CE 594667
<b>Conformity End Date</b>	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