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

Legal Manufacturer	eMoyoDotNet (Pty) Ltd trading as eMoyo, 1st Floor Silhouette House, 179 Beyers Naudé Drive, Northcliff, 2195, South Africa
Authorised Representative	PSF Medical BV, Marten Messweg 8, 3068AV Rotterdam, The Netherlands
Product	KUDUwave Audiometer
Product Configurations	Prime, Plus, Pro
Product Risk Classification	IIa as per Rule 10 of Annex IX
Standards Applied	BS EN 60645-1:2015, BS EN 60645-2:1997, BS EN 60601-1:2006, BS EN 60601-1-2:2002, BS EN 60601-1-6:2010+A1:2015, BS EN ISO 14971:2012, BS EN ISO 13485:2012, BS EN ISO 15223-1:2016, BS EN 1041:2008+A1:2013, BS EN ISO 14155:2011, BS EN 62304:2006 SANS 10083:2013
Notified Body	BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam
Notified Body Number	2797

eMoyo hereby declares that the above mentioned device conforms with the relevant provisions of the European Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC.

eMoyo declares that the product was assessed against Annex I of the European Council Directive 93/42/EEC and found to meet the essential requirements set out therein.

eMoyo declares that the electronic instructions for use of the above mentioned device conforms with the European Commission Regulation No 207/2012 of 9 March 2012.

The applied quality management system complies with the requirements of the European Council Directive 93/42/EEC (Annex V) and ISO 13485:2016 & EN ISO 13485:2016, certified by BSI (Certificate No. MD 682410). *eMoyo* agrees to fulfil the obligations imposed by the quality system and ensure continuous adequacy and efficacy.

BS EN ISO 14971:2012 Risk Management System has been applied and risks found have been deemed to be acceptable.

eMoyo agrees to maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines to the competent authorities.

eMoyo confirms that no medicinal product(s) within the meaning of Article 1 of Directive 2001/83/EC have been incorporated in the above mentioned device.

eMoyo agrees to inform the appointed Notified Body of any planned or unplanned significant change to the device schedule, including significant design change to devices and/or any change(s) to the quality management system.

eMoyo confirms that no other application has been lodged with any other Notified Body for the same product-related quality system.

This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.

Authorised Signatory:

Dr Dirk Koekemoer
Managing Director and Founder
Northcliff, South Africa

Valid From:

14 May 2019

Date