

EC Certificate Full Quality Assurance System: Certificate ES19/86937

The management system of

Chip Ideas Electronics, S.L.

C/ Clariano 8, Entresuelo B,
46021 Valencia. Spain

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 18 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 19 May 2016
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered ES/VLC 212333

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 2



Chip Ideas Electronics, S.L.

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

Electronic wireless stethoscope for detection and amplification heart, lungs, arteries or veins sounds and other internals sounds:

- eKuore Pro (Ref 0002)
- eKuore Pro - Volume raised (Ref EP0099)
- eKuore Pro - Amplified+ (Ref EP0098)
- eKuore One (Ref EB0002).
- eKuore One Wireless (Ref E1W0002)

Fonendoscopio electrónico inalámbrico para la detección y amplificación de sonidos cardíacos, pulmonares arteriales, venosos u otros sonidos internos:

- eKuore Pro (Ref 0002)
- eKuore Pro - Volume raised (Ref EP0099)
- eKuore Pro - Amplified+ (Ref EP0098)
- eKuore One (Ref EB0002).
- eKuore One Wireless (Ref E1W0002)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.