



# EC Declaration of Conformity



according to the Medical Devices Directive 93/42/EEC

*Class I Medical Device*

*(non-sterile, without measuring function)*

**Manufacturer:** Gnatus Equipamentos Médico-Odontológicos Ltda.

**Address:** Rodovia Abrão Assed, km 53 + 450m, CEP 14097-500  
Ribeirão Preto-SP, Brazil

**EC Representative:** Wellkang Ltd  
Suite B, 29 Harley Street, London W1G 9QR, UK

**We, the manufacturer, declare under our sole responsibility that**

<b>the medical device(s) of class</b>	Product Name	Type/model, identification of product allowing traceability (Where applicable)
	<b>Please refer in attached list</b>	
	according to annex IX of directive 93/42/EEC	<b>Class I Medical Device</b> (non-sterile, without measuring function)

**is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.**

Applied harmonised standards, national standards or other normative documents	EN ISO 15223-1:2012	EN 60601-1:2006/AC:2010
	EN 1041:2008	EN 60601-1-2:2007/AC:2010
	EN ISO 14971:2012	

Conformity assessment procedure: **Module A (EC Declaration of Conformity (Annex VII) + Technical Files)**

Notified Body (name & number): **NOT applicable**

Certificate & number

Signed on: 1 September 2015. Place: Ribeirão Preto, São Paulo, Brazil



Ricardo José Raveli  
Coord. da Garantia da Qualidade

Signature (on behalf of the manufacturer)

Name of authorized signatory: Ricardo José Raveli

Position held in the company: QA/RA Coordinator

## Product List

(Under MDD Directive 93/42/eec)

Product Name	Type/Models	Class
<b>Dental Chair</b>	Syncrus, Syncrus GL, Syncrus GLX, Syncrus G2, Syncrus G3, Syncrus G4, Syncrus G8.	<b>I</b> <b>(non-sterile, without measuring function)</b>
<b>Dental Light</b>	Persus L, Persus LED, Sirius G8 1 Led, Sirius G8 2 Leds, Sirius G8 Sensor 3 Leds, Sirius G8 Sensor 4 Leds, Sirius G8 Sensor 5 Leds, Sirius G8 Sensor 4 (2x2) Leds, Sirius G8 Sensor 5 (3x2) Leds.	<b>I</b> <b>(non-sterile, without measuring function)</b>
<b>Delivery Units</b>	Mini, Artus, Syncrus GLX, Syncrus H, Syncrus HLX, Syncrus LS, Syncrus G2, Syncrus G3, Syncrus G3 H, Syncrus G8 F, Syncrus G8 FE, Syncrus G8 H, Syncrus G8 HE.	<b>I</b> <b>(non-sterile, without measuring function)</b>
<b>Water Units</b>	Syncrus, Syncrus G1, Syncrus G2, Syncrus G3, Syncrus G4, Syncrus G4A, Syncrus G8, Syncrus Alcance 3T, Syncrus Alcance 3T V, Syncrus Alcance 3T BV, Syncrus Alcance 3T BV UE, Syncrus Alcance 4T, Syncrus Alcance 4T V, Syncrus Alcance 4T BV, Syncrus Alcance 4T BV UE, Syncrus Alcance 5T V, Syncrus Alcance 5T BV.	<b>I</b> <b>(non-sterile, without measuring function)</b>