

**DECLARACION CE DE CONFORMIDAD**  
**EC DECLARATION OF CONFORMITY**

**Depth of Anaesthesia Monitor**  
**Model: CONOX Lite**

**QUANTIUM MEDICAL**

La empresa QUANTIUM MEDICAL S.L con domicilio en:

Avinguda Ernest Lluch, nùm 32  
TecnoCampus, TCM2, 3.16, 3.17,3,18  
08302 Matarò, Barcelona, Spain

Declaramos bajo nuestra única responsabilidad que / We hereby declares under its own responsibility that:

1. El dispositivo mencionado anteriormente se aplicarán de conformidad con los requisitos de la Directiva 93/42/CEE relativa a los productos sanitarios (Implementado a nivel nacional por el Real decreto 1591/2009). Certificado N ° IT271818-1 Anexo II; emitido por el Organismo Notificador Bureau Veritas n. ID 1370) a través de la aplicación de las normas:  
*The above mentioned device has been produced in compliance with the Directive 93/42/EEC concerning Medical Devices and its amendments, Annex II requirements (which is adopted as national Law Decree n. 1591/2009) (certificate n° IT271818-1 issued by the notified body Bureau Veritas n. ID 1370).*
2. El dispositivo mencionado anteriormente debe ser considerada como perteneciente a la clase IIa (regla 10);  
*The abovementioned device is classified as IIa (Rules10) as active device for diagnosis*
3. Toda la documentación relativa al dispositivo se almacena en el Expediente Técnico y deberán conservarse por un periodo de al menos cinco años a partir de la fecha de fabricación del producto;  
*The documentation regarding this device is archived in the Technical File and maintained for a period of 5 years from the date of last manufacture of the device;*
4. Todas las fases de diseño y producción de este dispositivo cumplen los requisitos establecidos en el Sistema de Gestión de Calidad de la empresa como es requerido por el Anexo II de la Directiva de Dispositivos Médicos 93/42/EEC y sus enmiendas;  
*All design and production phases of this device meet the requirements set out in the company Quality Management System as required by Annex II of 93/42/EEC Medical Device Directive and its amendments;*
5. El Sistema de Gestión de Calidad de la empresa cumpla con los requisitos especificados en las normas ISO 13485:2016 certificado por TuV Body (certificados actual No. Q5 047402 0075);  
*The company Quality Management System comply with the requirements specified in ISO 13485:2016 standards and it is certified by TuV Body (current certificate No. Q5 047402 0075);*
6. QUANTIUM MÉDICA S.L. se ha comprometido a partir de ahora a establecer y mantener al día un procedimiento sistemático para revisar la experiencia adquirida con los productos en la fase posterior a la producción y para emplear los medios adecuados para aplicar las medidas correctivas necesarias,

incluida la obligación de notificar a la autoridad competente sobre los incidentes, inmediatamente después de su aprendizaje, involucrando a los productos;

*QUANTIUM MEDICAL S.L. is committed from now to institute and keep up to date a systematic procedure to review experience gained from devices in the post production phase and to implement appropriate means to apply any necessary corrective action, including the obligation to notify the Competent Authority about incidents, immediately on learning them, involving such devices;*



Mataró, Barcelona 29/11/2019  
Place and date of issue

Erik Weber Jensen, Chief Executive Officer, Quantum Medical  
Name (printed letters), position and signature of authorized person

# Annex I

Conox Lite Main Units are delivered with plugs dependent upon the standard local specifications:

Country	Code	Country	Code
Argentina	Z029242	Malaysia	Z029230
Australia	Z029292	Mexico	Z029282
Austria	Z029220	Nepal	Z029230
Bangladesh	Z029230	Netherlands	Z029270
Belarus	Z029256	Norway	Z029255
Belgium	Z029210	Pakistan	Z029230
Brazil	Z029240	Peru	Z029282
Chile	Z029281	Philippines	Z029232
China	Z029296	Poland	Z029293
Colombia	Z029282	Portugal	Z029243
Croatia	Z029253	Romania	Z029248
Czech Republic	Z029246	Russia	Z029256
Denmark	Z029257	Saudi Arabia	Z029233
Ecuador	Z029282	Singapore	Z029230
Egypt	Z029231	Slovakia	Z029244
Finland	Z029251	South Africa	Z029291
France	Z029210	South Korea	Z029295
Germany	Z029220	Spain	Z029280
Greece	Z029262	Sri Lanka	Z029230
Hong Kong	Z029230	Sweden	Z029250
Hungary	Z029245	Switzerland	Z029220
India	Z029230	Syria	Z029231
Indonesia	Z029231	Taiwan	Z029232
Iran	Z029231	Thailand	Z029236
Italy	Z029260	Turkey	Z029247
Japan	Z029298	United Kingdom	Z029230
Lebanon	Z029231	Vietnam	Z029231