



GIÁM ĐỐC

**INFINIUM** 

## DECLARATION OF CONFORMITY

Manufacturer : **Infinium Medical, Inc.**  
12151 62nd St. North #5 Largo, FL 33773 USA

European Representative : **OBELIS S.A.**  
Bd. Général Wahis, 53, 1030 Brussels, Belgium

Products: : **Operating Room Tables**

Products Models : **ATS**

Classification : **Class I According to Annex II of 93/42/EEC MDD**

Conformity Assessment Route : -

We herewith declare, under our own responsibility, that the following product (s) meets the provisions of the Council Directive 93 / 42 / EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied :  
*EN ISO 13485:2012, EN ISO 14971:2012, EN 62366-1:2015/AC:2015, EN 60601-1:2006, EN 60601-1-2:2007, EN 60601-1-4:1996, EN 60601-1-4:1996, EN 60601-2-46:1998, EN 1041:2008+A1:2013, EN 980:2008, EN 62304:2006*

Notified Body : **ALBERK QA TECHNIC**  
Barbaros Mah. Ak Zambak Sk. Varyap Grand Tower A Blok  
Kat: 19 Atasehir, Istanbul, 34746 Turkey with the identification number 2138

GMDN Code : **43364**



2138

Place, Date of Issue : **Largo, Florida USA, September 27, 2016**

Signature :



*Cengiz Kabakci, Management Representative for QMS*