



# DECLARATION OF CONFORMITY

Mod.

**AQ 0001**

Rev. N°.

05

Date:

30/10/2014

**Manufacturer:** 3A HEALTH CARE S.r.l.  
Via Marziale Cerutti, 90F/G  
25017 Lonato del Garda (BS)  
Italy

**Conformity assessment route:** Annex II (excluding section 4)  
in combination with Annex VII

**Product Description:** Compressor Nebulizers

**Class (MDD, Annex IX):** Ila

**Model (code):**

**A3 Complete (NE-C300-E)**

**3A HEALTH CARE S.r.l.**  
declares that the above mentioned product is in conformity with Medical Devices  
Directives 93/42/EEC and following updating.

**Applicable standards:**

EN 60 601-1:2006 ;  
EN 60601-1-2:2007 3<sup>a</sup> edition ;  
EN 13544-1:2009 ;  
EN 60 601-1-11:2010 ;  
EN 980:2008 ;  
EN 62366:2008 ;

UNI EN ISO 10993-1:2010 ;  
EN 10993-5:2009 ;  
EN 10993-10:2010 ;  
EN 14971:2012 ;  
UNI EN 1041:2013 ;

Lonato del Garda, 2014/10/30

In faith:

**Quality Manager**  
**Simone Abate**

**CE** 0434