

 <b>GESTIONE QUALITA'</b>	<b>DECLARATION OF CONFORMITY</b>	Mod. <b>AQ 0001</b>
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Rev. N°.	06		Date:	25/10/2017
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**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 Category:** Aerosoltherapy equipment

**Product Description:** Compressor Nebulizer

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

<b>Model (code):</b>
<b>A3 Complete (NE-C300-E)</b>

**3A HEALTH CARE S.r.l.**  
**declares under its sole responsibility that the above mentioned product and hereby  
declaration comply with the 93/42/EEC Medical Devices Directives, subsequent  
amendments and additions.**

**Applicable standards:**

EN 60601-1:2006 ;	UNI EN ISO 10993-1:2010 ;
EN 60601-1-2:2007 3 <sup>a</sup> edition ;	EN 10993-5:2009 ;
EN 13544-1:2009 ;	EN 10993-10:2010 ;
EN 60601-1-11:2010 ;	EN 14971:2012 ;
EN 15223-1:2016 ;	UNI EN 1041:2013 ;
EN 62366:2008 ;	

Lonato del Garda, 2018/03/14

In faith:  
Quality Manager  
Simone Abate

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**CE** 0051

Notified Body:  
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