

 <b>GESTIONE QUALITA'</b>	<b>DECLARATION OF CONFORMITY</b>	Mod. <b>AQ 0001</b>

Rev. N°.	06	Date:	03/05/2016
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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 Nebulizers

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

<b>Model (code):</b>
<b>C102 Total (NE-C102-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.**

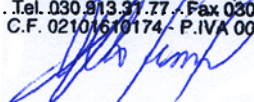
**Applicable standards:**

EN 13544-1:2009 ;	EN 60601-1:2006+A1:2013 (Ed3.1) ;
EN 15223-1:2016 ;	EN 60 601-1-2:2015 4 <sup>a</sup> edition ;
UNI EN 1041:2013 ;	EN 60 601-1-11:2015 ;
UNI EN ISO10993-1:2010 ;	EN 60 601-1-6:2010 ;
EN 10993-5:2009 ;	EN 62366:2008
EN 10993-10:2010 ;	EN 14971:2012 ;

Lonato del Garda, 2018/02/02

In faith:  
Quality Manager  
Simone Abate

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