

 <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>X105 Advanced (NE-C105-EO)</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.**

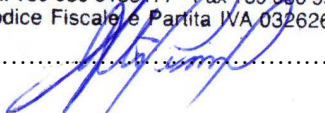
**Applicable standards:**

EN 13544-1:2007+A1:2009 ;	EN 60601-1:2006/A11:2011/A1:2013 ;
EN ISO 15223-1:2016 ;	EN 60601-1-2:2015 ;
EN 1041:2008+A1:2013 ;	EN 60601-1-11:2015 ;
UNI EN ISO10993-1:2010 ;	EN 60 601-1-6:2010+A1:2015 ;
EN 10993-5:2009 ;	IEC 62366-1:2015 ;
EN 10993-10:2010 ;	EN ISO 14971:2012 ;

Lonato del Garda, 2021/03/18

In faith:  
*Quality Assurance & Regulatory Affairs Director*  
**Simone Abate**

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**CE 0051**

Notified Body:  
IMQ S.p.A Italy No. 0051