

 GESTIONE QUALITA'	DECLARATION OF CONFORMITY	Mod. AQ 0001
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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

Model (code):
C28P (NE-C105-E)

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, 2020/12/15

In faith:
Quality Assurance & Regulatory Affairs Director
Simone Abate

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CE 0051

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