


DECLARATION OF CONFORMITY

Manufacturer	Name and address FOSHAN GAUNYING ELECTRONICS CO., LTD
	2nd Floor, Building 5, No. 1, Hua Bao South Road, Chan Cheng District, FoShan, Guangdong, P.R.C. Code:528000
European Representative	Name and address EMERGO EUROPE
	Molenstraat 15 2513 BH, The Hague, The Netherlands
Product	Name, type and /or model Mesh nebulizer
	NM215, IH55, SIH46
Classification	Class, rule according to Annex IX of the MDD as amended by 2007/47/EC
	Class IIa ,Rule 11
Conformity Assessment Route	Annex Applied MDD Annex VII and V
<p>We herewith declare that the above mentioned products meet the provisions of the LVFS2003:11 transposing the Council Directive 93/42/EEC as amended by 2007/47/EC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.</p>	
Standards Applied	<p>List of (Harmonized) Standards for which documented evidence of compliance can be provided</p> <p>IEC60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC60601-1-11:2010 ISO 14971:2007/EN ISO 14971:2012 EN 1041:2008 ISO 10993 series IEC 62366:2007 EN 13544:2009 EN 980:2008</p>
Notified Body	Name, Identification Number Intertek Semko AB NB 0413
(EC) certificate (s)	EC certificate (s) Number (s) 41315556
Start of CE-Marking	Date, lot No. or Serial No. of first CE-marking From 2008 SN XXXX XXXXXX SAMPLE:NOV.2015 SN 1511 000001
Place, Date of Issue	City, Date FOSHAN , GUANGDONG PROVINCE IN CHINA Feb, 07,2017
Signature	<i>Ladi lee</i> 
	Name Ladi lee Position General manager