

**Declaration of Conformity**

**MDC**

**Valid: Jan 01 2009 till Dec 31 2009**

**MEDICAL DEVICE DIRECTIVE 93/42/EEC**



**Manufacturer: Baby's Breath Ltd**  
**Ha'hadas St., North Industrial Area**  
**P.O Box 42 Or-Akiva 30600**

We, Baby's Breath Advanced Inhalation Technologies, located in North industrial zone, Or-Akiva, Israel, manufacturers of inhalation systems for infants, as detailed hereunder, that are placed in the European market, declare that our products conform and meet the essential requirements set out in Annex I and according to design requirements set out in Annex II of the Medical Device Directive EEC 93/42 EEC. We have pointed MDC, ID 0483 Kriegerstraße 6 / D-70191 Stuttgart, Germany, to act as our notified body.

<b><u>Product(s)</u></b>	<b><u>Classification</u></b>	<b><u>Followed</u></b>
BabyAir	Ila	Annex IX Rule 2

Within these requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed Mr. Alfred Eckert, Zum Klosterbruehl 32 D-66636 Tholey Germany to act as our Authorized Representative in the European Community.

Baby's Breath manufacturing is conforming with ISO 13485:2003 and to ISO 9001:2000

  
 BABY'S BREATH LTD.  
 513078943  
 Golan Gilad, CEO

Date: Feb 11, 2009

Name: Golan Gilad	Date: 11/02/09	Signature:
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