Version No.10.2	**Hisense Ltd.**	**EC DECLARATION OF CONFORMITY** **COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 Concerning Medical Devices**

DECLARATION OF CONFORMITY

ACCORDING to ANNEX VI and ANNEX III of the MEDICAL DEVICE DIRECTIVE 93/42/EEC, as amended by 98/79/EC, 2000/70/EC, 2001/104/EC and 2007/47/EC

We: HISENSE Ltd., 23 Becker St., Rishon LeZion, 75359, Israel

declare that the BABYSENSE Infant Movement Respiratory Monitor (Model CU-100/2 rev D.) is in conformity with the essential requirements and provisions of Annex VI and Annex III of the Medical Devices Directive 93/42/EEC and are exclusively responsible for this declaration.

The product is classified as Class IIb, in accordance with Rule 10, Annex IX of the Directive.

Standards to which conformity is declared:

EN 60601-1:2006
EN 60601-1-2:2007
EN 60601-1-6:2010
EN 62366:2008
EN 980:2008
EN 1041:2008
EN ISO 14971:2012
EN ISO 13485:2012

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01/08/2013