Hisense Ltd.

Version No.10

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.

Notified Body:

LNE No. 0459

1 rue Gaston Boissier

75724 PARIS Cedex 15, France

Authorised Representative:

Obelis S.A.

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> Haim Shtaryd HISENSE Ltd. Rishon Le Zion, Israel 25/08/2013