

Version No. 4	Hisense Ltd.	EC DECLARATION OF CONFORMITY COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 Concerning Medical Devices
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EC DECLARATION OF CONFORMITY

We : HISENSE Ltd.
10, Shmotkin St., Rishon Le Zion, Israel


Declare hereby that our product - BABYSENSE Infant Movement Respiratory Monitor (Models CU-100 and CU-100/2), class IIb devices according to Annex IX of the 93/42/EEC Directive, is in conformity with the Directive provisions applying to this product.

This declaration is based on the following elements:

- Product technical and related files demonstrating conformity with the Directive essential requirements - see EC-Type Examination Certificate No. 0155/B3/2 for Annex III Point 3, Directive 93/42/EEC concerning Medical Devices.
- Approval of our Production Quality Assurance System - see EC Certificate of Approval No. 0110/B6/1 for Annex VI Point 3, Directive 93/42/EEC concerning Medical Devices.

The CE Marking will be applied according to Article 17 of the Directive 93/42/EEC.

The evaluating Notified Body: G MED No. 0459
33 Av. Du General Leclerc
92260 Fontenay Aux Roses, France


Haim Shtalryd
HISENSE Ltd.

Rishon Le Zion, 04/09/04