15/9/2019

DECLARATION OF CONFORMITY

According to Annex II of the MEDICAL DEVICE DIRECTIVE 93/42/EEC

HISENSE Ltd., 27 Shaked Street, Hevel Modi'in Industrial Park 731990, Israel, declares that the BABYSENSE Infant Movement Respiratory Monitor (Model CU-100/2) is in conformity with the essential requirements and provisions of Annex II excluding section 4 of the Medical Devices Directive 93/42/EEC and is exclusively responsible for this declaration.

The BABYSENSE Infant Movement Respiratory Monitor is marketed under the following commercial names:

Babysense 7	CU-100/2 Rev E Monitor with two Sensor Pads
Babysense 1 pro	CU-100/2 Rev E Monitor with one Sensor Pad
Babysense 2 pro	CU-100/2 Rev E Monitor with two Sensor Pads (One rectangular sensor and one round sensor)
Babysense 1	CU-100/2 Monitor with one Sensor Pad
Babysense II	CU-100/2 Monitor with two Sensor Pads
Babysense 5	CU-100/2 Rev D Monitor with two Sensor Pads

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

Notified Body: GMED No. 0459
1 rue Gaston Boissier
75015 PARIS Cedex 15, France

Authorized Representative: Obelis s.a
Bd. Général Wahis 53
1030 Brussels, BELGIUM

Technical File Reference – TFCU100/2Revision 29 dated 15.9.2019
Applicable GMED certificate no. – 29824 (rev. 4)

Hisense Ltd. also declares that the product meets the applicable provisions of Council Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (GMED certification is according to 93/42/EEC directive only).

Yaniv Shtalryd
HISENSE Ltd.
Hevel Modi'in Industrial Park, Israel
15.09.2019

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