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 7319900, 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 Connect	CU-100/2 Rev F Monitor with two Sensor Pads, Basic UDI-DI: 7290119471002FQQ
Babysense 7	CU-100/2 Rev E Monitor with two Sensor Pads, Basic UDI-DI: 7290119471002EQN
Babysense 8	CU-100/2 Rev E Monitor with two Sensor Pads, Basic UDI-DI: 7290119471002EQN
Babysense 1 pro	CU-100/2 Rev E Monitor with one Sensor Pad, Basic UDI-DI: 7290119471002EQN
Babysense 2 pro	CU-100/2 Rev E Monitor with two Sensor Pads (One rectangular sensor and one round sensor), Basic UDI-DI: 7290119471002EQN

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

EU Notified Body:	GMED No. 0459 1 rue Gaston Boissier 75015 PARIS Cedex 15, France
EU Authorized Representative:	Obelis s.a Bd. Général Wahis 53 1030 Brussels, BELGIUM

Technical File Reference – TFCU100/2.

Applicable GMED certificate no. 29824 (rev. 7) and GMED additional document no. 38134 (rev. 3) and GMED Notified Body confirmation letter no. 39899 (rev. 1).

Hisense Ltd. also declares that the product meets the applicable provisions of Council Directive 2011/65/EU and Council Directive 2015/863 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).

Elad Erdan, General Manager

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