UKCA MDR 2002 DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of Angelcare Corporate UK Ltd. We hereby declare that the medical device specified below complies and meets the requirements of **Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002] (Production Quality Assurance System)**

The declaration is based on:

- **Manufacturers Name:** Angelcare Corporate UK Ltd
- **Manufacturers Address:** Suite 6, Brooms Road, Stone Business Park, Stone, Staffordshire. ST15 0TL
- **Name of the Device**: (Angelcare) Baby Movement Monitor with Video and Sound
- **Product code**: AC25-1
- **Intended Purpose:** Angelcare baby monitors are lifestyle products intended to assist parents and carers in a baby's daily care. The Monitor alerts parents /carers after 20 seconds if no movement is detected through mattress. Movements can be any movement and include breathing movements. The monitors are not a substitute for parental or medical supervision.
- **GMDN Code**: 36319
- **Classification with rule number**: Class IIa, Annex IX Rule 10
- **Conformity assessment route**: **Annex V - Part II of The Medical Devices Regulations 2002, Annex V,** Conformity assessment based on a quality management system and on assessment of technical documentation.
- **Approved Body Name and address**: **SGS United Kingdom Limited (UK Approved Body number 0120)** - Rossmore Business Park, Ellesmere Port, South Wirral, Cheshire, CH65 3EN
- **Standards applied**: Refer to the tables below for standards applied and applicable certificates.

Product Description		Angelcare Baby Movement Monitor with Video and Sound
No.	**Document No. / edition**	**Title & Report No.**
Class IIA UKCA Medical device - Annex C - Part II of the Medical Devices Regulations 2002, Annex V (as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002 (Production Quality Assurance System)		
External Testing facilities: For all testing except below and SGS ISO 13485 QMS, Intertek Testing Services Hong Kong Limited. Addr.: 2/F Garment Centre, 576 Castle Peak Road, Kowloon, Hong Kong SAR, China EN 60601-1:6:2020 ----- ITS Shanghai Intertek Testing Services Shanghai. Addr.: Building 86, No. 1198 Qinzhou Road (North), Shanghai 200233, China		
Medical		
1	EN 60601-1:2005/A1:2012 /A2:2020	Medical Electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A2:2020)

2	EN 60601-1-2:2015/A1:2021	Medical Electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014/A1:2020)
3	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
4	EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes (IEC 62304:2006)
5	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) UKAS
6	EN 60601-1-6:2010/A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010/A2:2020)
7	EN 62366-1:2015/A1:2020	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007/A1:2014)

8	EN 60601-1-11:2015/A1:2020	Medical electrical equipment - Par 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11: 2015/A1:2020)
9	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021)
Non-Medical		
10	Directive EU 2015/863	RoHS 3 - The Restriction of Hazardous Substances
11	Directive 2006/66/EC	Batteries and accumulators and waste batteries - Heavy metal content
12	REACH 1907/2006	SVHC not exceeding limits for customer notification - Organotin, PAH, Cadmium tested
13	Regulation 1275/2008 including EN 50564:2011	Power consumption standby and off mode
14	The Radio Equipment Regulations 2017	Implementing Directive 2014/53/EU

	Article 3.1 (a) - Health & Safety -	
15	BS EN 62368-1:2014 + 2017 (second Edition)	UKCA Audio, Video, IT equipment - Part 1: Safety Requirements
16	EN 62479:2010	Human exposure restrictions EMF
17	EN 50385:2017	Human exposure restrictions EMF
	Article 3.1 (b) - EMC -	
18	EN301 489-1 V2.2.3	EMC Part 1 - Common technical requirements
19	EN301 489-17 V3.2.4	EMC Part 17 - Specific requirements for broadband
20	EN 55032: 2015:2020	EMC Emissions
21	EN 55035: 2017:2020	EMC Immunity
22	EN 61000-3-2: 2014	EMC - Harmonic Current Emissions
23	EN 61000-3-3:2013	EMC - Voltage changes, fluctuations in public
	Article 3.2 - Radio	
24	EN 300 328 V2.2.2	Wideband & Data transmission equipment 2.4GHz
	Additional due diligence below	
25	ASTM F2951-19	U.S Baby Monitors Standard
26	EN71-1:2018	Physical & Mechanical only - EU Toy Safety (not a toy)

27	EN71-2:2020	Flammability - EU Toy Safety (not a toy)

Signature:

NAME: Archana Sridharan

FUNCTION: Quality Engineer (Angelcare Corporate UK Ltd)

10 June 2024