By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 764870 R000

Manufacturer: Owlet Baby Care, Inc.

Address:
3300 N Ashton Blvd, Suite 300
Lehi
Utah
84043
USA

Single Registration Number: US-MF-000026112

EU Authorised Representative: OBELIS S.A

Address:
Bd. Général Wahis, 53
1030 Brussels,
Belgium

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-04-08**

Current Issue Date: **2024-04-08**

Starting Validity Date: **2024-04-08**

Expiry Date: **2029-04-07**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Infant vital sign monitors	Intended for routine, in-home surveillance of infants by measuring oxygen saturation (SpO2) and pulse rate (PR). Software analyses photoplethysmography data to identify instances when the infant's PR and/or SpO2 moves outside a preset range, and provides a notification to the caregiver, prompting them to assess the infant. The notifications and associated data are intended to supplement the decision by caregivers to seek additional guidance for medical care of the infant. The feature is not intended to replace traditional methods of diagnosis and/or treatment.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3615395	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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