



Declaration of Conformity


Product Family: Circadiance SleepWeaver Masks
Rule & Class: Rule 2; Class IIa (Masks)
Assessment Route: Annex II, (Excluding Section 4) Full Quality Assurance
Accessories: Tether Strap (Optional) P/N 100638 (Class I)
 Hose Clip (Optional) P/N 100775 (Class I)

Manufacturer	Authorized Rep.	Notified Body
Circadiance LLC 1300 Rodi Road Turtle Creek, PA 15145 USA Toll Free: 1 888 825 9640 Tel: +1 724 858 2837 Fax :+1 412 202 4583	EMERGO Europe Prinsessegracht 20 2514 AP, The Hague The Netherlands +31 (0)70 345 8570	GMED 1, rue Gaston Boissier 75724 Paris, Cedex 15, France NB #0459 Certificate No: 18982 (EC) Certificate No: 18981 (ISO 13485:2016)

Circadiance hereby declares that the below mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices, as amended by 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Circadiance confirms that no other application has been lodged with another Notified Body for the same device related Quality Management System.

APPROVAL

Name	Title	Signature	Date
Chris Esasky	Manufacturing Engineer		2/20/2020

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Product Description	REF	GMDN*	Start Date
SleepWeaver Advance Nasal CPAP Mask	100274, 100277, 100281, 100285, 100289, 100291, 100293, 100295, 100332, 100336, 100343, 100358, 100359, 100360, 100361, 100425, 100435	57815	Sept. 3, 2010
SleepWeaver Advance Pediatric Nasal CPAP Mask	101319, 101320, 101321, 101322, 101323, 101324, 101325, 101326, 101327, 101328, 101334	57815	Nov. 9, 2015
SleepWeaver Advance Small Nasal CPAP Mask	101224, 101225, 101226, 101227, 101228, 101229, 101230, 101231, 101232, 101233	57815	June 13, 2014
SleepWeaver Élan Nasal CPAP Mask	100481, 100482, 100483, 100484, 100485, 100518, 100519, 100520, 100521, 100522, 100563, 100635, 100653, 100654, 100655, 100656, 100657, 100663, 100664, 100665, 100666, 100667, 100727, 100728, 100729, 100730, 100731, 100742, 100743, 100744, 100745, 100746, 100782, 100630	57815	Sept. 18, 2012
SleepWeaver Anew Full Face Soft Cloth PAP Mask	100954, 100955, 100956, 100957, 100958, 100959, 100960, 100961, 100962, 100963, 100964, 100965, 100966, 100967, 100968, 100969, 100970, 100971, 100972, 100973, 100974, 100975, 100976, 100977, 100978, 100979, 100980, 100981, 100982, 100983, 101084, 101145	57814	June 7, 2013
SleepWeaver 3D Nasal Mask	101496, 101516, 101517, 101486, 101491, 101698, 101699, 101728	57815	Nov. 1, 2016

*GMDN Description

GMDN Code	Term
57814	CPAP/BiPAP Face Mask, Resusable
57815	CPAP/BiPAP Nasal Mask, Resusable

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Revision History

Rev.	Date	Author	Description	Change Order
01	01/10/2019	R. Lordo	Initial release converting from date control to revision control.	50850
02	02/20/2020	C. Esasky	Addition of Part Number 101728 to SleepWeaver 3D Nasal Mask product list and removal of 100477 FeatherWeight tube due to having a separate DoC.	50879