

EU MDR Declaration of Conformity			
Document Number: BR-EUDOC-MDR-001	Version Number: 2.00	Issue Date: 12/03/2021	Valid Until: N/A

Identification of the Legal Manufacturer:	Foundation Consumer Brands LLC 106 Isabella Street, Suite 602 Pittsburgh, PA. 15212 USA
Identification of EU Authorised Representative:	Brandshapers Ltd Ballytramon Business Park Ardcavan, Castlebridge Co. Wexford, Y35 Y19A Ireland

This Declaration of Conformity is issued under the sole responsibility of Foundation Consumer Brands LLC acting in the capacity of legal manufacturer.

Basic Unique Device Identifier (UDI):	081007180AAA0000CE
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Single Registration Number (SRN):	US-MF-000001882
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Identification of the device(s) concerned:	Product Description	Size / Colour	Formulation
	Breathe Right Tan	Small / Medium	173019
		Large	173036
	Breathe Right Clear	Small / Medium	173037
		Large	173299
	Breathe Right Mentholated	Small / Medium	174426
		Large	173300
	Breathe Right Tan Extra	Not applicable	N/A – Not currently marketed
	Breathe Right Clear Extra	Not applicable	N/A – Not currently marketed
	Breathe Right Mentholated Extra	Not applicable	N/A – Not currently marketed
	Breathe Right Kids	Blue	173092
		Green	173093
		Purple	N/A – Not currently marketed
	Breathe Right Lavender	Not applicable	173643

Trade Names:	Breathe Right
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Intended Purpose of Device:	The Breathe Right nasal strips is a non-sterile, non-prescription, disposable external nasal dilator intended to be used to enhance breathing by reducing nasal airflow resistance. The nasal strips can reduce or eliminate snoring by enhancing nasal airflow and provide relief from nasal congestion due to cold, allergies and structural causes (septal deviation).
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Risk Classification:	Class I, Non-Sterile, as per Rule 1 in Annex VIII (non-invasive device with no other rule applying)
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We hereby declare that the above-mentioned devices comply with the European Medical Devices Regulation 2017/745				
European Directives and Regulations:	Medical Devices Regulation 2017/745			
Relevant Standards:	Standard	Version	Equivalent EU Harmonised Standard (if available)	
	N/A	N/A	EN 1041:2008	
	ISO 13485	2016	EN ISO 13485:2016 +AC:2016	
	ISO 14971	2019	EN ISO 14971:2019	
	ISO 10993-1	2009	EN ISO 10993-1:2009	
	ISO 10993-1	2018	N/A	
	ISO 10993-5	2009	EN ISO 10993-5:2009	
	ISO 10993-10	2010	N/A	
	ISO 10993-18	2009	EN ISO 10993-18:2009	
	ISO 15223-1	2016	EN ISO 15223-1:2016	
	ISO / TR 24971	2020	N/A	
	IEC 62366	2007	EN 62366:2008	
	IEC 62366-1	2015	N/A	
	IEC 62366-2	2016	N/A	
	ISO 16142-1	2016	N/A	
Name and Address of Notified Body:	Not applicable			
Conformity of Devices:	Annex II & Annex III			
Applicable CE Certificate(s):	Not applicable			
Quality System Certificate:	Foundation Consumer Brands LLC maintains a quality system to control the processes it performs as the manufacturer of the identified devices.			
Identification of the person authorised to sign on behalf of Foundation Consumer Brands LLC (Person Responsible for Regulatory Compliance):	Signature:			
	Name:	Douglas Flint		
	Title:	Person Responsible for Regulatory Compliance		
	Place of Issue:	Foundation Consumer Brands LLC 106 Isabella Street, Suite 602 Pittsburgh, PA. 15212 USA		
	Date:	12/03/2021		