OSCIMED SA
Rue Fritz-Courvoisier 105
CH-2300 La Chaux-de-Fonds
Switzerland

Email : info@oscimedsa.com
Phone : +41 32 926 63 36
www.oscimedsa.com

EC DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

Manufacturer Name and address	**OSCIMED SA** Fritz-Courvoisier 105 CH-2300 La Chaux-de-Fonds Switzerland	Phone : +41 32 926 63 36 Email : info@oscimedsa.com Web : www.oscimedsa.com
Actor ID/SRN Code	CH-MF-000009605	
Authorized Representative Name and address	**OSCIMED EUROPE SAS** Rue Denis Papin 44 ter FR-25300 Pontarlier France	Phone: +41 32 924 50 42 Email: info@oscimed-europe.com
EU(EC) Rep ID/SRN Code	FR-AR-000028943	
Basic UDI-DI	764010492NOSNORINGBELTV8	

We hereby under our sole responsibility declare, that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and full fills the General Safety and Performance Requirements, including Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2023/988 on General Product Safety (GPSR).

Products covered by the present Declaration of Conformity:

Intented purpose	Anti-snoring POSIFORM BELT is intended for reducing positional snoring trouble
Medical Device Family	Anti-snoring devices
Medical Device Name	Anti-snoring Belt
Brand Name	POSIFORM BELT
Reference Manufacturer UDI-DI	**POSIFORM BELT Anti-snoring electronic belt - One size** ref.: P-01 764010492 756 3
Accessory / Ref UDI-DI	**Fabric Belt** ref.: P-01-BLT 764010492 757 0

Technical file ID & issue Date	R037_TECH-03/A, 24.03.2025
GMND code UMDNS code	Not available 16223 - Anti snoring positioning device
Class / Rule	I – Rule 13
	According to annex VIII of the European Medical Device Regulation 2017/745.
Justification	According to rule 13, all other active devices are classified as class I.
This declaration is based on	EN ISO 13485:2016 EN ISO 14971:2019 EN 62366-1:2015/Cor1:2016 EN 60601-1:2006 + A2:2021 IEC 60601-1-2:2014 + A1:2020 EN 60601-1-11:2015 EN ISO 10993-1:2018
The conformity assessment procedure has been conducted under our own responsibility.	
Conformity assessment procedure	(UE) MDR 2017/745, Annexe IX
Certification body / *Registration*	SQS / IQNet, EN ISO 13485:2016, Reg. no. CH-43733, validity: 11.06.2026
Swissmedic registration	*Manufacturer registration: CHRN-MF-20003026* *Device registration: CH-202503-0042*

This Declaration of Conformity consist of 2 pages and is issued by Jacques Magnin in his function as Deputy Manager on the 15th of October 2025.

Place, date	Name and function
La Chaux-de-Fonds, Switzerland 15.10.2025	Jacques Magnin Deputy Manager