



DECLARATION OF CONFORMITY

Manufacturer	Circius Pharma Södra Långebergsgatan 34-36, SE-436 32 Askim, Sweden
Device classification and rule (Regulation EU 2017/745 Annex VIII)	I, Rule 1
Manufacturers SRN	SE-MF-000013023

Basic UDI-DI	735013396Otovent1TV
EMDN (CND)	Q03040199 (CND)

Product and Trade Name	Otovent®
Size/Variants	1-pack/5-pack/10-pack/15-pack/Adult/Replacement Balloons

Intended Purpose: Otovent is intended for treatment of negative pressure in the middle ear

Conformity assessment based on Technical Documentation per **Annex II and III of Regulation (EU) 2017/745**.

This declaration of conformity is issued under the sole responsibility of Circius Pharma AB as the manufacturer. I hereby declare that the above-mentioned devices comply with the **Regulation (EU) 2017/745** concerning medical devices.

Askim, 2025-01-24

Place and date of issue

Maria Carlsson
Person responsible for Regulatory Compliance
On behalf of Jan G. Smith, CEO

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