

DECLARATION OF CONFORMITY

Manufacturer	Circius Pharma AB Södra Långebergsgatan 34-36, SE-436 32 Askim, Sweden
Manufacturer SRN	SE-MF-000013023

Basic UDI-DI	735013396Otinova1QC
Device classification (93/42/EEC, Annex IX)	Class I
GMDN Code	58472, Drying Otic Solution

Product / Trade name	Otinova®
Size / Variants	1x15 mL

Intended Purpose:
Otinova is used to treat ear canal inflammation/eczema, also known as Swimmer's Ear (otitis externa).

I hereby declare that the above-mentioned devices comply with Annex VII of LVFS 2003:11 transposing EC Directive 93/42/EEC concerning medical devices.

Each batch of product is released for sale in accordance with records certifying compliance with specifications.

This Declaration of Conformity is in compliance with the Transitional Provisions, Medical Device Regulation (EU) 2017/745, Art. 120.

Circius Pharma AB

Askim, 2025-01-24

Place and date of issue

A handwritten signature in blue ink, appearing to read "Maria Carlsson".

Maria Carlsson

Person Responsible for Regulatory Compliance
On behalf of Jan G. Smith, CEO