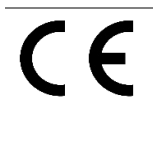


# Otoscope speculum

## Dormo

### > Product description

The DORMO®-SPEC product is an ear speculum designed to be inserted into the patient's external ear. It is attached to an otoscope that emits a beam of light through the speculum to explore the ear cavity up to the eardrum.



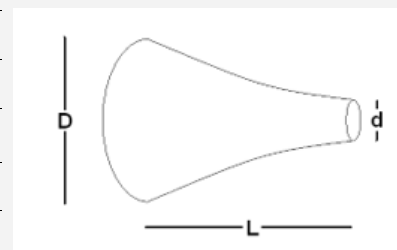
### > Technical specifications

#### > Materials

- Speculum: PP, non-toxic colorant
- Packaging: Cardboard case

#### > Main dimensional properties

Reference	d(mm)	D(mm)	L(mm)
4030	4.0	18.6	35.0
4040	2.5	18.6	35.0
4050	4.0	14.25	29.0
4060	2.5	14.25	35.0
4090	2.5	15.6	34.5
4095	4.0	15.6	26.0
4070	2.5	14.25	35.0
4080	4.0	14.25	29.0
4010	2.5	23.8	37.5
4020	4.0	23.8	37.5
4100	4.0	15.5	32.6



Measurements of diameters (D and d) are internal

### > Compatibility

Reference	Company	Patient	Compatibility
4030	Riester	Adult	E-Scope, RI-Mini, Ri-Scope L1/L2, Pen –Scope
4040		Pediatric	E-Scope, RI-Mini, Ri-Scope L1/L2, Pen –Scope
4050		Adult	E-Scope, RI-Mini, Ri-Scope L1/L2, Pen –Scope
4060		Pediatric	E-Scope, RI-Mini, Ri-Scope L1/L2, Pen –Scope
4090		Pediatric	Ri-Scope L3
4095		Adult	Ri-Scope L3
4070	Heine	Pediatric	Beta 400, Beta 200, K 180, Mini 3000
4080		Adult	
4010		Pediatric	Beta 100, K100
4020		Adult	
4100	Welch-Allyn	Adult	All diagnostic otoscopes

### > Biocompatibility

- No cytotoxic (ISO 10993-5)
- No sensitizing (ISO 10993-10)
- Negative intracutaneous irritation test (ISO 10993-10)

*Conclusion: the product is biocompatible.*

*This product does not contain natural latex, phthalates or compounds of animal or biologic origin.*

### > Sterilization and expiry date

- Non sterile product.
- Shelf life: 5 years after the manufacturing date.

### > Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Single use product. No maintenance required.

**> Packaging**

#	Ref	Packaging
TOKXX	4XXX	<ul style="list-style-type: none"><li>• Dispenser case with 250 units.</li><li>• Service box contains 4 dispenser cases (1000 units).</li></ul>

**> Instructions for use**

- Before using the product, select the appropriate size and model for the otoscope used.
1. Fit the speculum on the diagnostic otoscope.
  2. After lighting up the device, insert the speculum into the patient's outer ear for the examination.
  3. Upon completion, remove the speculum from the otoscope and dispose of it in accordance with the protocol established.

**Date:** May 2023**Specification N°:** ETP/153/ 9**> Regulatory information**

TELIC, S.A.U. guarantees that this product is in conformity with Regulation (UE) 2017/745. and that it has been manufactured following the directives of the Quality Assurance System certified as ISO 13485.

This product is classified as:

- Class I product according of Annex VIII of Regulation (UE) 2017/745., rule 1.
- GMDN code: 35348 Self-retaining ear speculum
- UMDNS code: Z12021085 ( Endoscopy instruments- consumables).