auditdata

*Your Partner in Audiology Solutions*

## Declaration of Conformity

According to Medical Device Directive (MDD) 93/42/EEC and RoHS Directive 2011/65/EU

**Manufacturer**

Auditdata A/S
Dalbergstroeget 5-7
2630 Taastrup
Denmark

**Conformity Assessment Procedure**

Annex II of Medical device Directive
MDD 93/42/EEC

**Registration**

Danish Health and Medicines Authority
Axel Heides Gade 1
2300 Copenhagen S, Denmark

CE

**Product Identification**

| | |
|---|---|
| Category: | Video Otoscope |
| Brand: | Primus |
| Model: | PVO |
| Lot/Batches/Serial number: | From SW release 2.1.0.0 and Otoscope S/N 2200343 |

**MDD Directive**

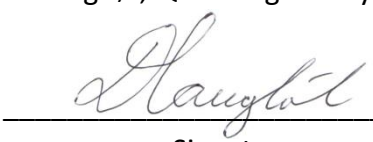
Class I, Rule 12, MDD
93/42/EEC

The medical device is in compliance with the essential requirements according Annex I of the Medical Device Directive 93/42/EEC and RoHS Directive 2011/65/EU

We declare under our sole responsibility that the products, to which this declaration relates, are in conformity with the Essential Requirements Annex I of the above directive.

Taastrup, August 2nd 2018

Dan Haugbøl, QA & Regulatory Manager



Signature