

Creator: Nicholas Petry

## EU Declaration of Conformity

PPE Description:

**Soft Silicone** – A stable silicone that is malleable and is used as a circumaural earplug, with noise attenuation and water proofing protection.

**Brand names:**

Aqua Ears, Soft Silicone, BioEars, Oronproppar, Boots Ultra-soft Silicone, Silikonproppar, German BioEars, Propartner 2 Pair

**Manufactured by:**

Cirrus Healthcare Products LLC, 60 Main Street P.O. Box 220, Cold Springs Harbor, NY 11724 USA  
Cirrus Healthcare Products LLC, 136 Hills Court P.O. Box 910, East Dorset, VT 05253 USA  
Cirrus Healthcare Products LLC, 10 Crystal Business Centre, Ramsgate Road, Sandwich, Kent, CT13 9QX UK

This declaration of conformity is issued under the sole responsibility of the manufacturer:  
Cirrus Healthcare Products LLC.

**Object of the declaration:**

Traceability will be completed with; PO numbers on the product located next to the product identification #, on the shipping carton a lot #'s will be added to track shipment level items, shipment will also be recorded to pinpoint shipment locations. All records will be kept for 5-year past expiration date.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

Hearing protectors' general requirements - EN 352-2:2002 Standard date: April 2003.

**The notified body:**

INSPEC International Ltd. 56 Leslie Hough Way, Salford, Gt Manchester M6 6AJ, England (Notified Body No: 0194) performed the EU type-examination (Module B) and issued the EU type-examination certificate # 1953

INSPEC International B.V. Beechavenue 54-62, 1119 PW, Schiphol-Rijk, Netherlands (Notified Body No: 2849) performed the EU type-examination (Module B) and issued the EU type-examination certificate # 1953

The PPE is subject to the conformity assessment procedure conformity to type based on quality assurance of the production process (Module D) under the surveillance of the notified body:

INSPEC International Ltd. 56 Leslie Hough Way, Salford, Gt Manchester M6 6AJ, England (Notified Body No: 0194)

INSPEC International B.V. Beechavenue 54-62, 1119 PW, Schiphol-Rijk, Netherlands (Notified Body No: 2849)



Soft Silicone Earplugs

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Additional information:

Signed for and on behalf of Cirrus Healthcare Products LLC.  
136 Hills Court, East Dorset, VT 05253, USA

Issue Date: 12/21/2020

Jose Monegro, Director of Production and Distribution

Nicholas Petry, QA and Engineering Supervisor