

WARNING LETTER

To: All Icare® customers
From: Ari Tiukkanen, CEO, Icare Finland Ltd.

Dear Icare® tonometer customer,

We wish to bring to your attention that the replacement probe tips being marketed and sold by Tonometer Tips, LLC are **not**, despite the representations on that company's website, "authorized" by Icare Finland or "approved by the FDA."

Icare Finland's products, including genuine replacement probe tips for its FDA-cleared Icare® tonometer, are sold through a network of authorized independent representatives. Tonometer Tips, LLC is **not** such an authorized representative.

Icare Finland's probe tips for its Icare® tonometer are subject to strict quality control procedures during manufacture. Absent these quality control procedures, Icare Finland cannot warranty the safety and performance of its Icare® tonometers. Icare has **no** control of the quality of any probe tips not made by Icare specifically for its Icare® tonometer, including the probe tips being sold and marketed by Tonometer Tips, LLC.

FDA 510K

Icare FDA number: **K063873**

Regulation number: 21 CFR 886.1930

Icare® probe tip is a component of the FDA-cleared, Icare® TA01i device. There is no third party, FDA-cleared or approved, authorized probe tip on the market for the Icare® TA01i device.

Warranty

Icare Finland's products carry a 2 year (24 months) parts and labor warranty to the end-user against defects in materials and workmanship; provided that the product has been used in accordance with user manuals and other accompanying instructions given by Icare Finland. What is more, the use of components, equipment and consumables that are not authorized by Icare Finland, including replacement probe tips, may result in a denial of warranty coverage.

Global Product Liability

Icare Finland is covered by third party liability insurance against any bodily injury or material damage caused to a third party by Icare Finland's activities or products. Coverage can be denied by the use of components, equipment and consumables that are not authorized by Icare Finland, including replacement probe tips.