2024-10-30

Statement on clinical data for Oticon JET 2 BTE

The clinical data held by the manufacturer for the devices in question comprise clinical evaluation[1] (including systematic literature reviews, validation, and usability activities), and post market clinical follow-up (PMCF)[2] in accordance with EU MDR 2017/745 (as amended) and applicable international standards.

In addition to the clinical data, the devices have been thoroughly verified according to the applicable general and particular international standards for hearing aids ensuring the technical and clinical performance are compliant and state-of-the-art.

Sincerely,

Anja Ravn
Manager, Clinical Affairs

Digitally signed by Mojila Violetta
Date: 2024.11.14 16:33:41 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

1 “Clinical Evaluation – Demant Platform Velox & Velox S” Doc. No. 0901c76e80a8caff

2 DOC-10000866 Post-market Clinical Follow-up Report

Oticon A/S
Kongebakken 9
2765 Smørum
Denmark

Main +45 3917 7100
CVR no. 42334219

info@oticon.com
www.oticon.global