

Statement on clinical data for Oticon PLAY PX 2 miniBTE & PG10 BTE SP

The clinical data held by the manufacturer for the devices in question comprise clinical evaluation¹ (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

Anja Ravn
Manager, Clinical Affairs

1 "Clinical Evaluation – – Demant Platform Polaris 22.1" Doc No.: 0901c76e80a8c806 & "Clinical Evaluation – Demant Platform Velox & Velox S" Doc. No. 0901c76e80a8caff

2 PMCF investigation 02 & PMCF investigation 03 in "Post-market Clinical Followup Report" Doc. No. 0901c76e80a6cf91

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